**Code Break Testing Procedure**

**Name of Trial: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ R&D ref. No.: \_\_\_\_\_\_\_\_\_\_\_\_\_ Date of test: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time of test: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Tested by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Test Patient Details: ­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| --- | --- | --- |
| Task | Comments | Pass/Fail |
| Name of initial emergency code break contact as defined by the emergency code break procedure for the study |  |  |
| Was the emergency code break contact contactable on the number available in the Sponsor File / Pharmacy File? |  |  |
| If No, were you given an alternative contact? |  |  |
| If Yes, was the emergency code break contact named on the delegation log for this purpose? |  |  |
| Name of person who dealt with code break request |  |  |
| How long did it take to speak to the correct emergency code break contact and how many people did you have to speak to get to them? |  |  |
| Was the contact able to obtain the Clinical Trial Code Break Request Form (FRM029)? |  |  |
| Did the emergency code break contact request the appropriate information before proceeding to action the code break? |  |  |
| Did the emergency code break contact know how to access the relevant trial information? e.g. protocol, delegation log, IRT system access, Pharmacy File |  |  |
| Did the emergency code break contact have up to date IRT system knowledge? (if applicable) |  |  |
| Did the emergency code break contact follow the correct procedure according to the emergency code break procedure for the study?  |  |  |
| Did the emergency code break contact inform the Investigator of the emergency code break after the event? (if applicable) |  |  |
| Did the emergency code break contact inform the Sponsor of the emergency code break after the event? (if applicable) |  |  |

See next page for marking criteria.

Code break test: **Pass or Fail** (delete as appropriate)

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Actions for follow up:**

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**This form should be filed in the Sponsor File**

**Marking Criteria - A fail on any of the tasks marked with an \* would indicate an overall fail**

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| --- | --- |
| Task | Pass/Fail Criteria |
| \*Name of emergency code break contact as defined by code break procedure for study | Pass: Clear identification in code break procedureFail: No delegated person identified in code break procedure |
| \*Was the emergency code break contact contactable on the number given? | Pass: Contact details up to date and adequateFail: Contact details incorrect or insufficient alternative numbers given |
| \*If No were you given an alternative contact? | Pass: The name and number of a delegated deputy was easily available Fail: No delegated deputy identified either in the code break procedure or within team |
| \*Was the contact named on the delegation log for this purpose? | Pass: Contact is named on delegation log specifically for unblinding purposesFail: Contact not named on delegation log or named but for other purposes. |
| Name of person who dealt with unblinding request | N/A |
| \*How long did it take to speak to the correct contact and how many people did you have to contact to get to them? | Pass: 1 or 2 people contacted, obtained correct contact within 2 hoursFail: More than 2 people contacted or taken over 2 hours to speak to correct contact |
| Was the emergency code break contact able to obtain the Clinical Trial Code Break Request Form (FRM029)? | Pass: YesFail: No |
| \*Did emergency code break contact request the appropriate information before proceeding to action the code break? | Pass: YesFail: No – inadequate details requested (\*parts of FRM029 not completed) |
| \*Did the emergency code break contact know how to access the relevant trial information? E.g. protocol, delegation log, IRT system access, Pharmacy File | Pass: Upon questioning, the emergency code break contact could describe where they would look for the informationFail: Above not possible |
| \*Did the emergency code break contact have up to date IRT system knowledge? (if applicable) | Pass: The contact confirmed they knew their access and how to access the systemFail: Unaware of own access or how to obtain it |
| \*Did the contact follow the correct procedure according to the emergency code break procedure for the study?  | Pass: YesFail: No |
| \*Did the emergency code break contact inform the Investigator  | Pass: YesFail: No |
| \*Did the emergency code break contact inform the Sponsor? | Pass: YesFail: No |