**Amendment Approval/Acknowledgement Emails:**

* **Substantial Amendment**

**Email Subject:**

Substantial Amendment - R&D Ref XXXXXXXXX **Protocol No** **XXXXXXXXXXX** Substantial Amendment X (01.01.09)

Dear Dr X,

**R&D Ref**: XXXXXXXXX    **Ethics Ref**: XX/XXXXX/XX

**Investigator**: Dr X

**Project Title**: A Phase II, Single Arm, Single Agent, Multicentre, Study….

**Protocol Number: XXXXXXXXXXX**

**Amendment: Substantial** Amendment X (01.01.09)

**Sponsor**:

I am pleased to inform you that R&D have reviewed the above study's Amendment X (01.01.09) and can confirm that Management Approval is still valid for this study.

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| Reviewed Documents:  | Version | Date |
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I wish you every success with this research project.

Yours sincerely,

Research and Development Department

cc. Sponsor, CRO, Regulatory Administrator, etc