E-SUBMISSION GUIDE FOR SUBSEQUENT NOTIFICATION OF CLINICAL RESEARCH USE (CRU)

Subsequent can be made if there is a need as follows:

1) **The addition of medical devices**
2) **The addition of study sites and medical devices**
3) **Any changes to applicant details information, study sites or medical devices that have not yet completed the importation process.**

Medcast Notification Form	Explanation
SECTION A : APPLICANT INFORMATION	
All information in Section A are open for editing. So, applicant can delete or update any information that is not up to date, irrelevant etc.	Extra Information - Applicant can provide summary about the subsequent. e.g. This is a subsequent application to add new trial site/ to add new list of devices. Changes of the device need to be made because…
SECTION B : RESEARCH INFORMATION	
All information in Section B are open for editing, except : 1. Purpose Of Research 2. National Medical Research Registry (NMRR) Registration ID : 3. Protocol No.	Same requirement as in E-Submission guide for New Notification of CRU.
SECTION C : RESEARCH SITE INFORMATION	
All information in Section C are open for editing. So, applicant can delete or update any information that is not up to date, irrelevant etc.	Please upload latest Ethic approval letter.
SECTION D : MEDICAL DEVICE INFORMATION	
All information in Section D are open for editing. So, applicant can delete or update any information that is not up to date, irrelevant etc.	Same requirement as in E-Submission guide for New Notification of CRU.
SECTION E : IMPORTATION ENTRY POINT	
All information in Section E are open for editing. So, applicant can delete or update any information that is not up to date, irrelevant etc.	Same requirement as in E-Submission guide for New Notification of CRU.