

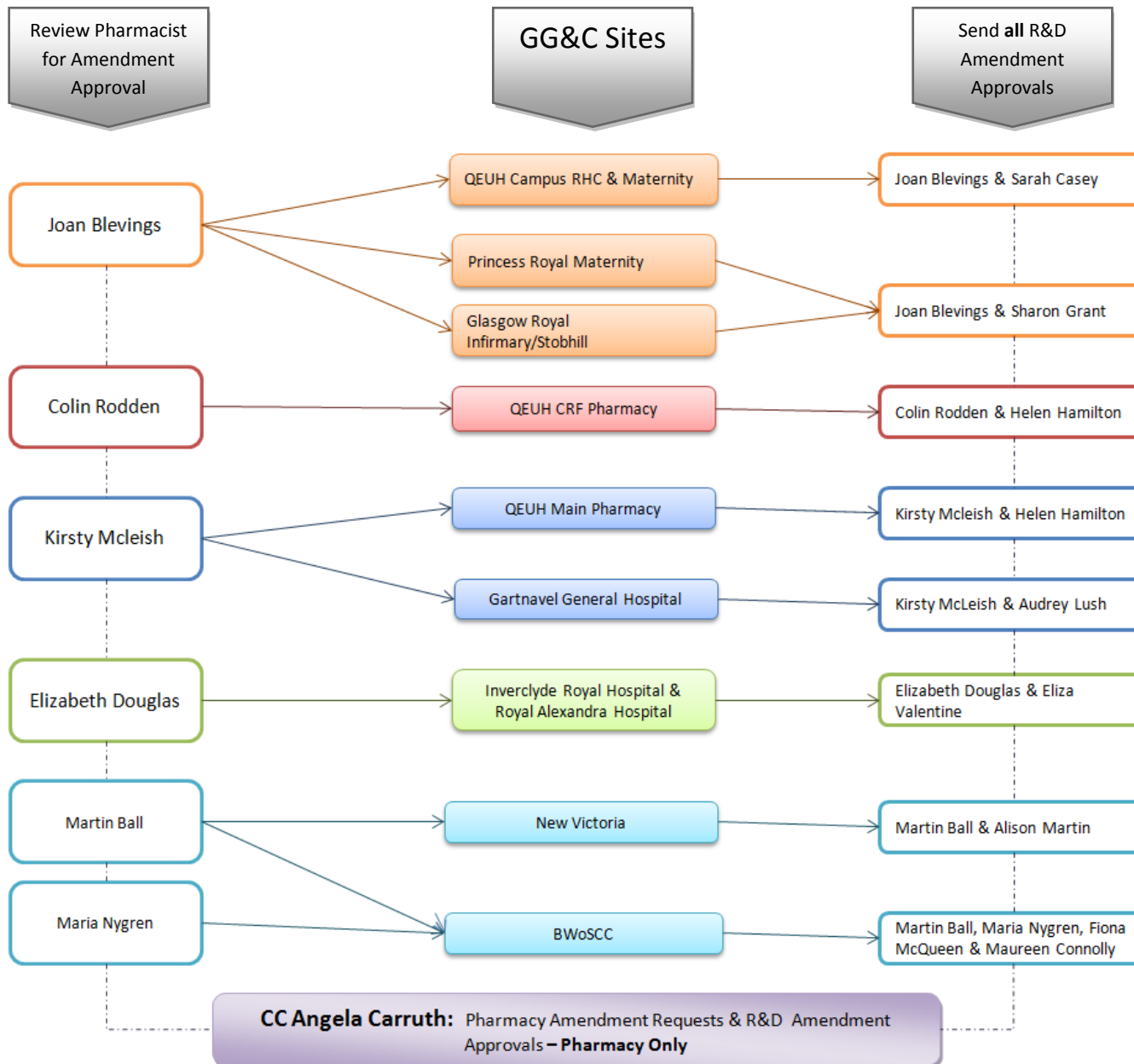
Guideline 52.003A Pharmacy Clinical Trials Amendment Approval Guidance

Pharmacy Clinical Trials – Pharmacy Review Checklist

Pharmacy Review Checklist	Pharmacy Approval Required	Information Only - email approval to Site Pharmacist and Technician(s)	No Action Required
IMP change in how it is administered	X		
Reformulation of IMP	X		
IMP change in dose	X		
Changes to cycle/length of supply	X		
Amendment with an updated IMP Dossier	X		
Change to Study Documents - Patient Information Sheet (PIS) or Consent Form (CF)	X		
Change to Study Documents - Protocol (<i>changes affecting IMP</i>), IB, Pharmacy Manual or IWRS Manual	X		
Extension of a study	X		
Issue of an updated Investigator's Brochure	X		
New NHS GG&C Site (hosted study)	X		
Inclusion/exclusion criteria	X		
Updated safety profile of IMP	X		
Change in funding arrangements		X	
Changes to the radiation dose given to a participant		X	
Temporary halt to recruitment of a study		X	
Re-start to recruitment of a study		X	
Any amendment which includes an MHRA approval		X	
Change to Study Documents - Protocol (excluding IMP)		X	

Change to the design methodology of a study		X	
Change to the definition of the end of the study (e.g. 10 year follow-up changed to 'until death')		X	
Addition to local study team		X	
Change in Sponsor		X	
Change in Sponsor contact details		X	
Change in Chief Investigator		X	
Change in Principal Investigator at one of our sites		X	
Change of number of patients recruited		X	
New researcher/SSI form for site already approved			X
Changes in the logistical arrangements for storing samples			X
Changes in the logistical arrangements for transporting samples			X
Changes to the requirement of an ARSAC certificate			X

Pharmacy Clinical Trials – Amendment Approvals



Prepared by: Joanne McGarry

Signed:

Dated:

Approved by: Melissa Robert

Signed

Dated:

Document History

Version	Date	Description
V1.0	14/07/2016	Released to staff

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