

Johns Hopkins Bayview Medical Center

GENERAL CLINICAL RESEARCH CENTER

GCRC Research QA Program

Policy No: 153

Original Date: 9/12/2002

Previous Date: none

Reviewed Date: none

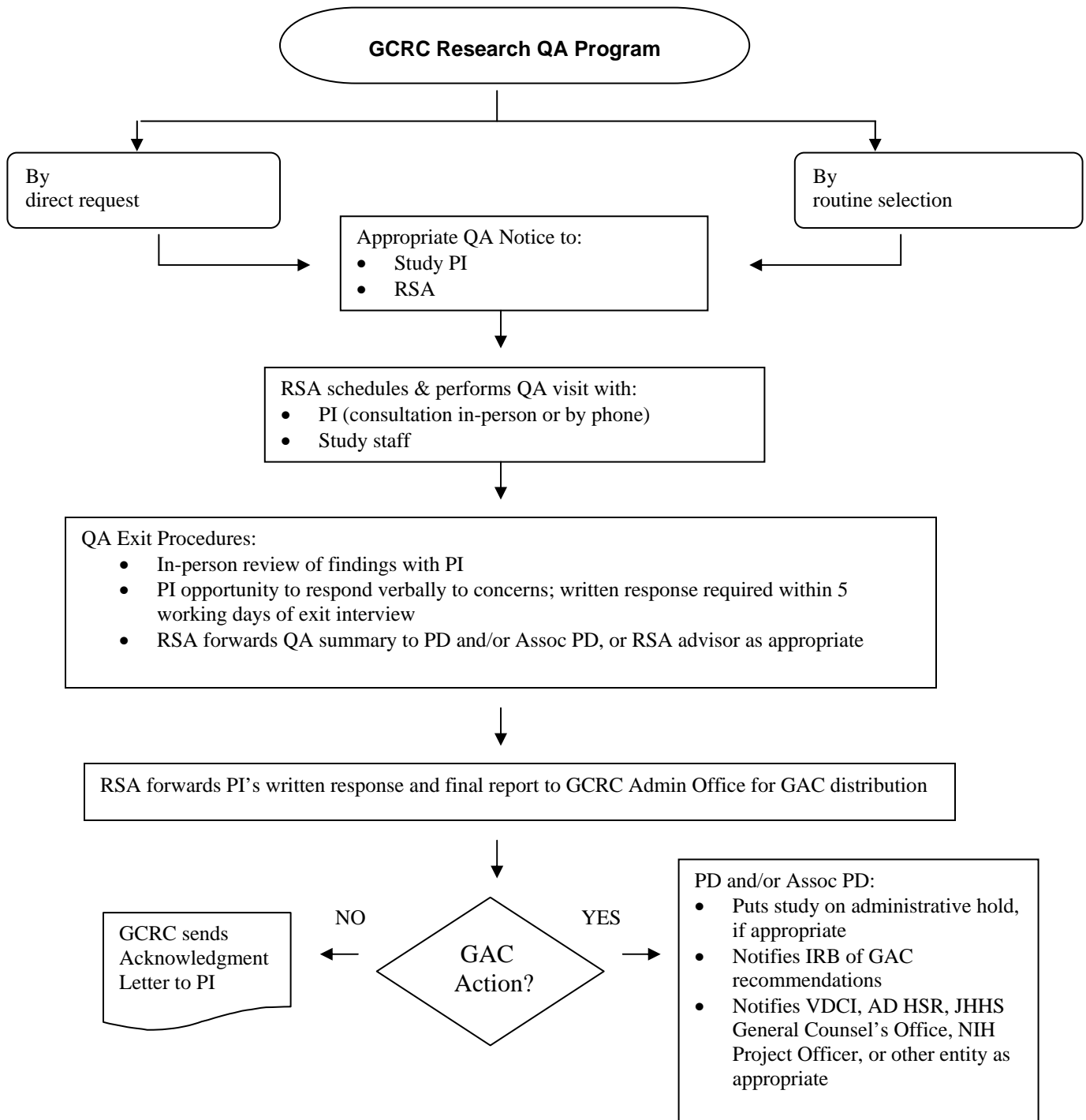
Purpose: To define the process utilized to assess study adherence for research studies conducted on or as part of the GCRC.

Policy: The National Advisory Research Resources Council (NARRC) recommends that each GCRC ensure that the protocol carried out on the GCRC complies with the IRB- and GAC-approved protocol.

QA visits will be conducted for each GCRC approved protocol at least once per calendar year. Additional visits may be required if legitimate concerns have been raised by the GCRC Program Director and/or Associate Program Director, Manager or Director of a GCRC Core Service, or research subjects.

Procedure: Diagram on page 2.

Procedure:



Key:

RSA – Research Subject Advocate

PD – Program Director

Assoc PD – Associate Program Director

VDCI – Vice Dean for Clinical Investigation

AD HSR – Assistant Dean for Human Subjects Research

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Originator: Research Subject Advocate

Reference: Recommendations to General Clinical Research Centers (GCRCs) for Patient Safety in Clinical Research

Pamela Ouyang, MD
Program Director, GCRC