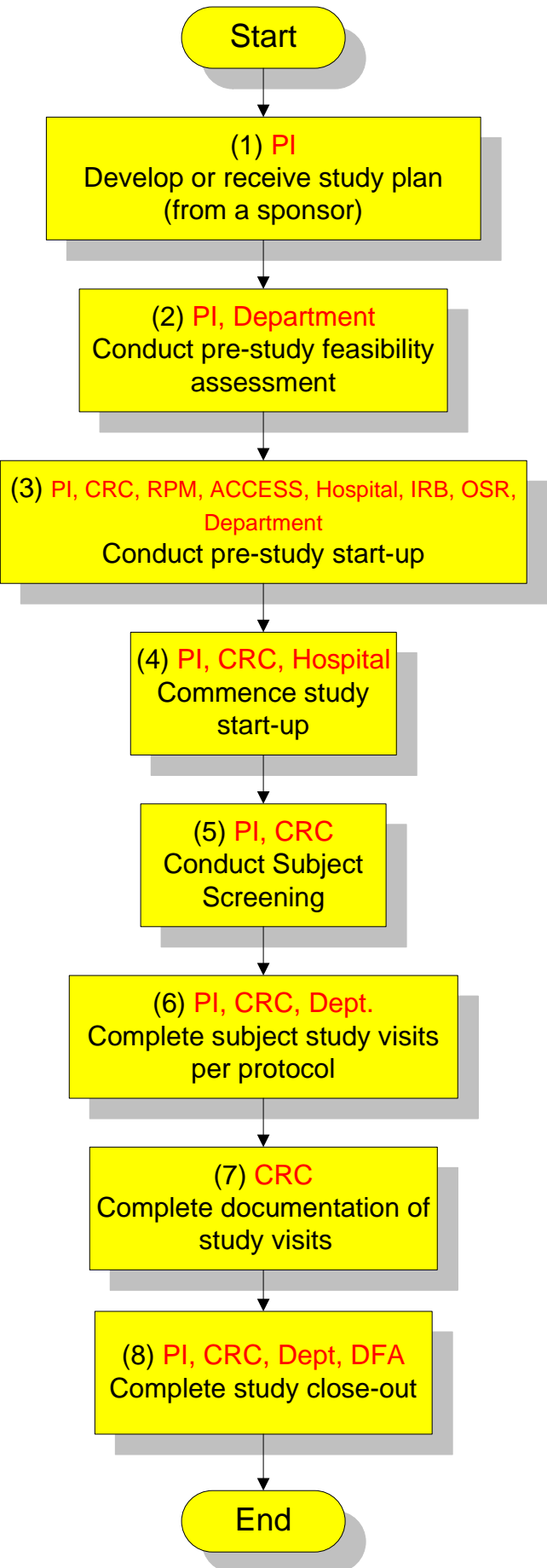
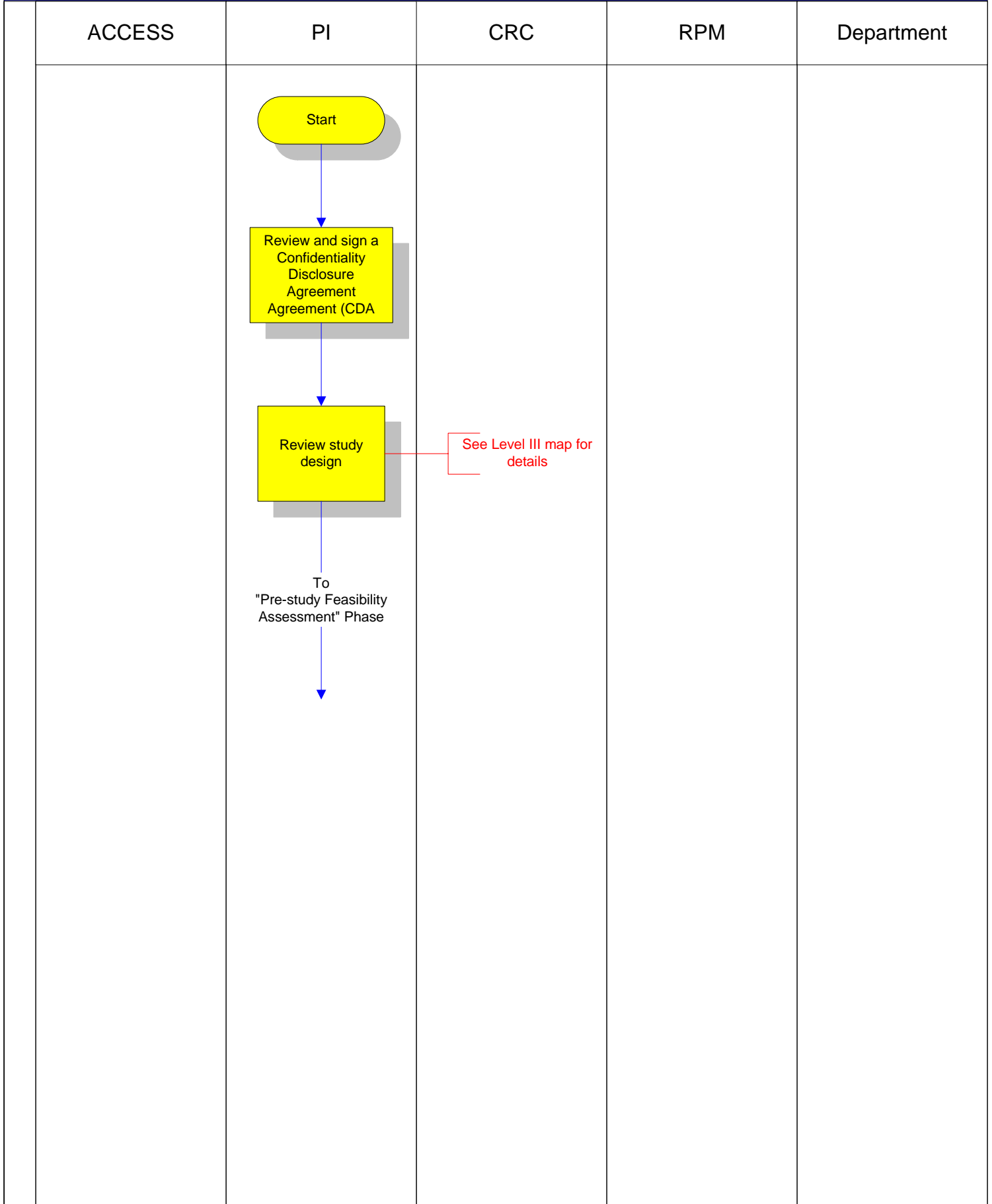


Clinical Trials Process Level I Map



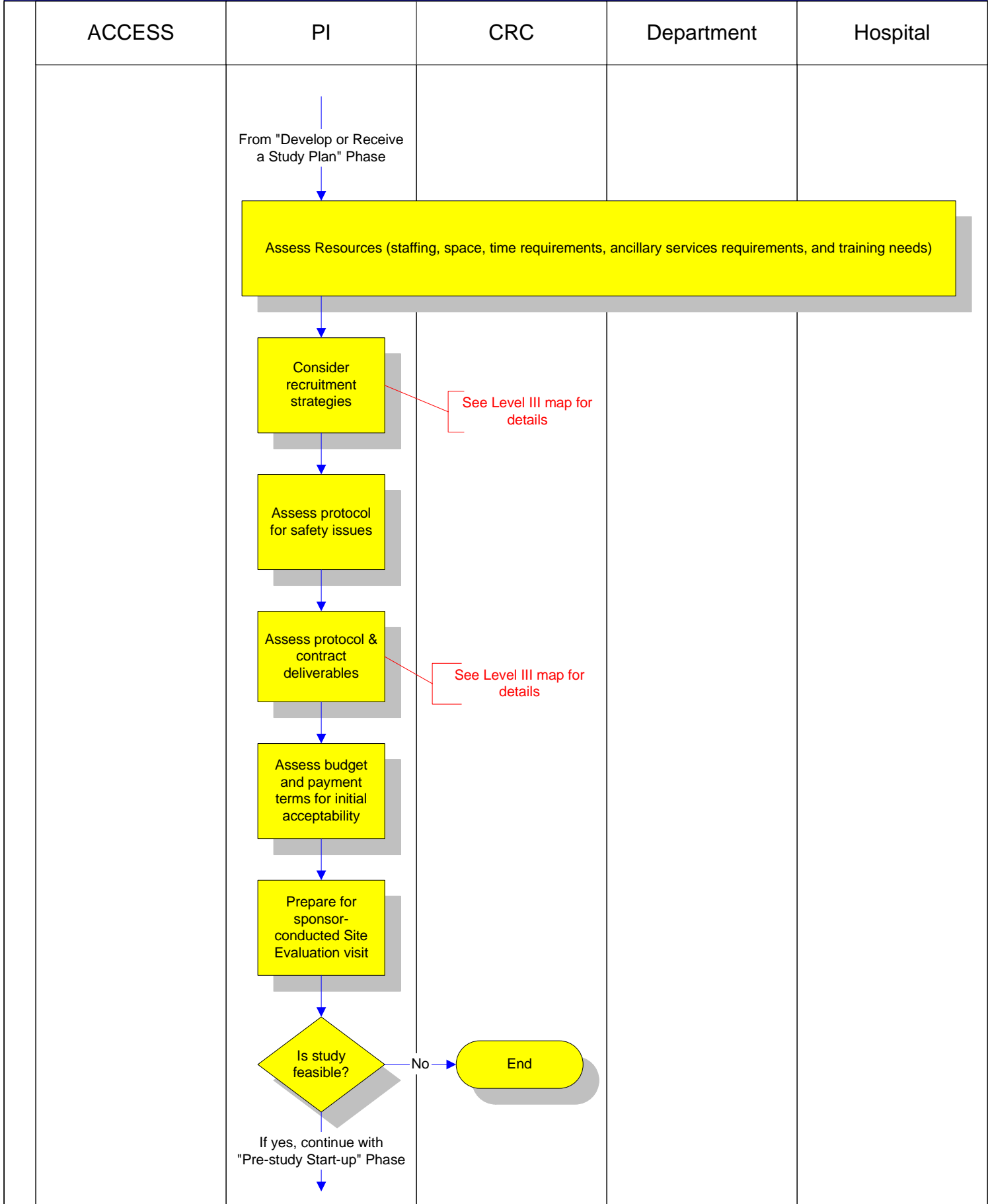
# Clinical Trials Process Level II Map

## Develop or Receive Study Plan (from a sponsor) Phase



# Clinical Trials Process Level II Map

## Pre-study Feasibility Assessment Phase



See Level III map for details

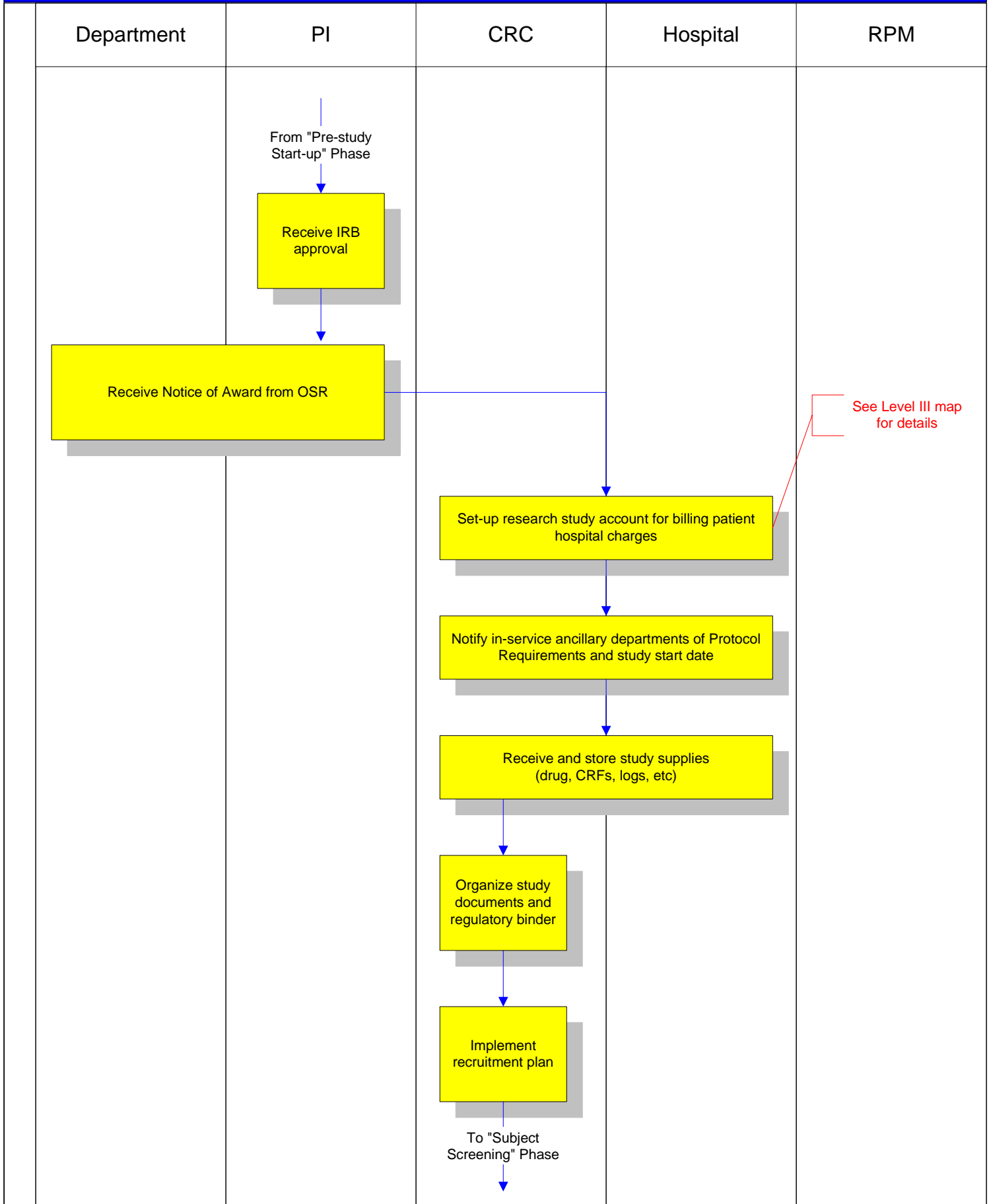
See Level III map for details

If yes, continue with "Pre-study Start-up" Phase



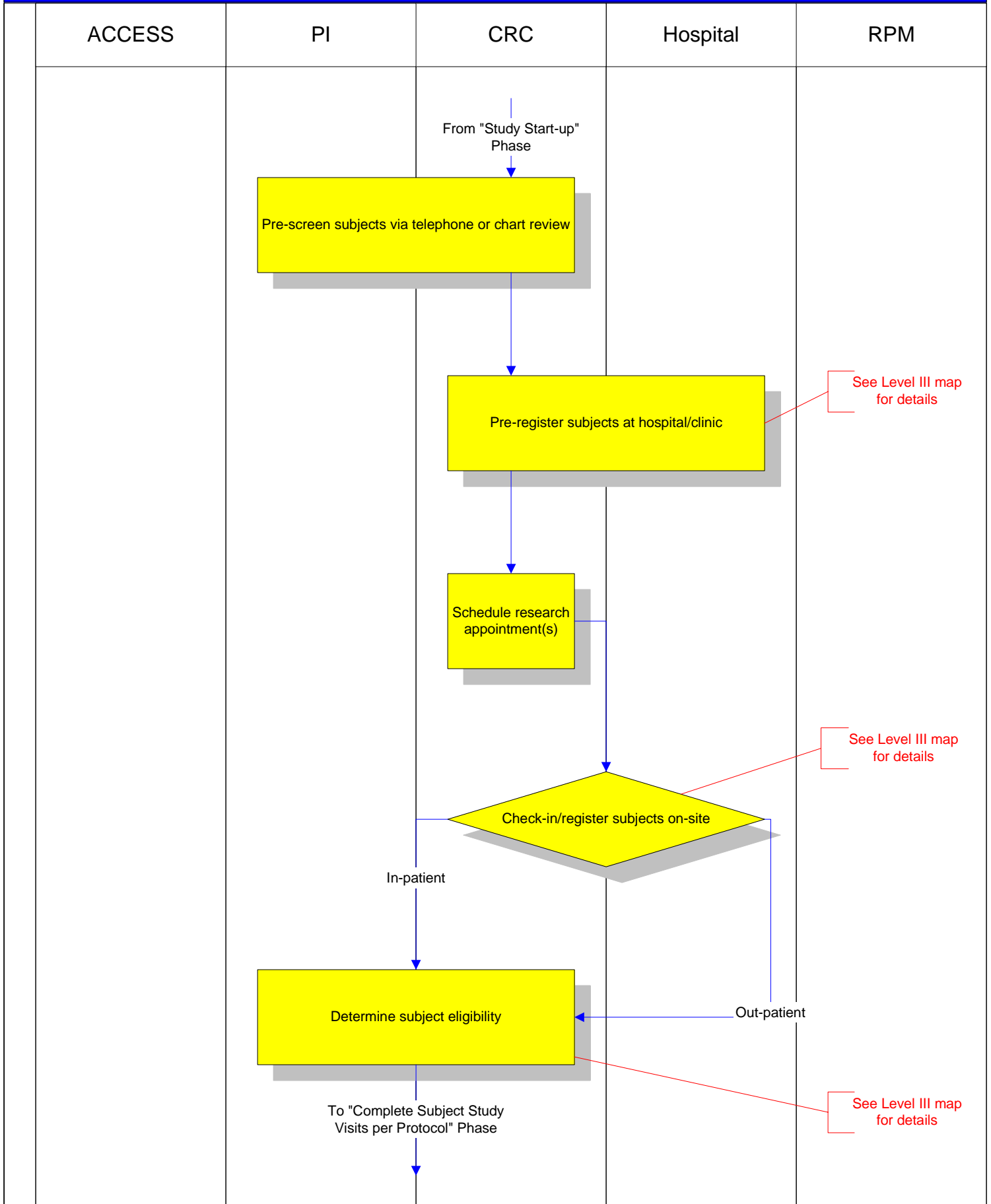
# Clinical Trials Process Level II Map

## Study Start-up Phase



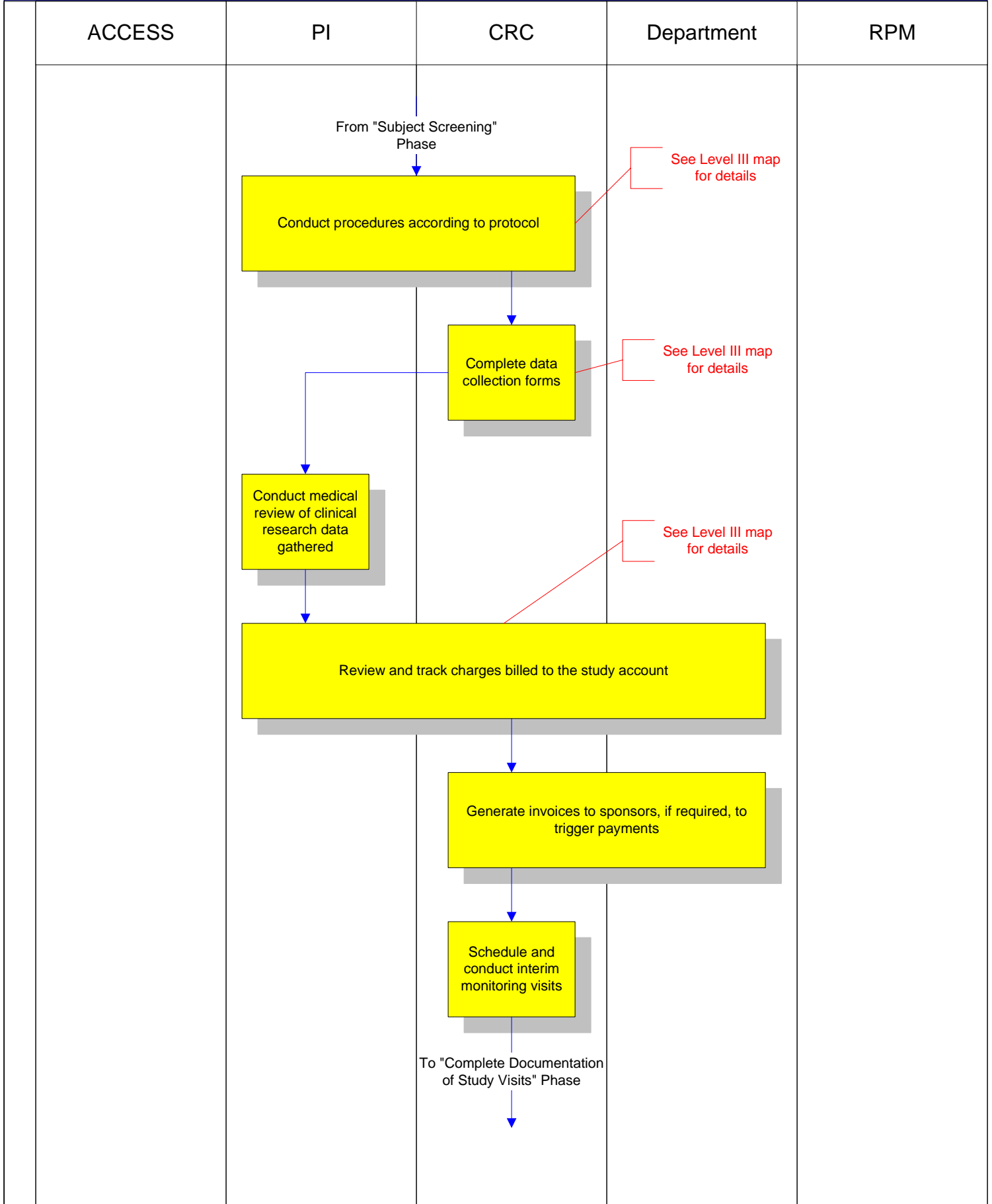
# Clinical Trials Process Level II Map

## Subject Screening Phase



# Clinical Trials Process Level II Map

## Complete Subject Study Visits Per Protocol Phase



See Level III map for details

See Level III map for details

See Level III map for details

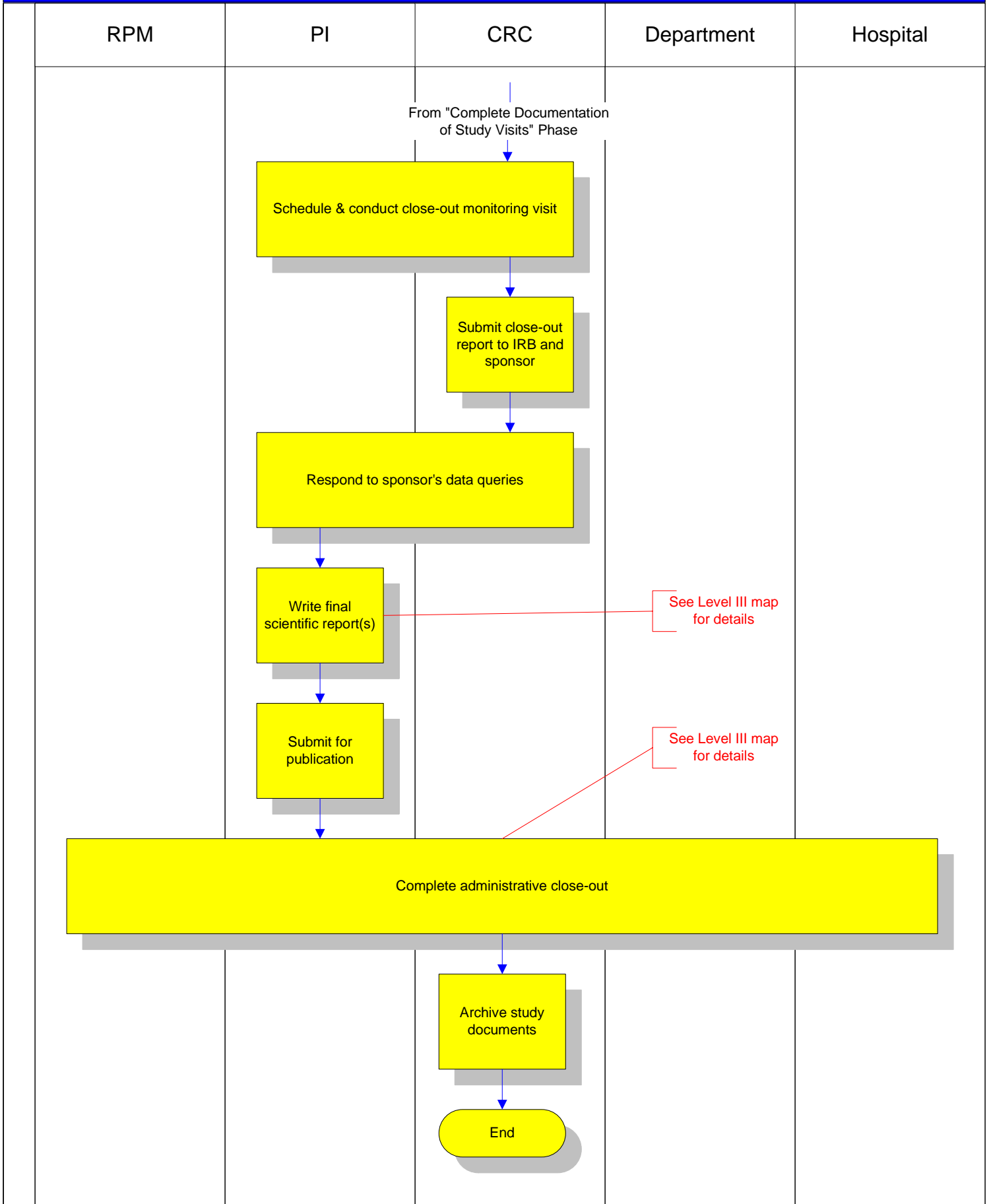
# Clinical Trials Process Level II Map

## Complete Documentation of Study Visits Phase

	ACCESS	PI	CRC	Department	RPM
			<p>From "Complete Subject Study Visits per Protocol" Phase</p> <p>↓</p> <div style="border: 1px solid black; background-color: yellow; padding: 5px; width: fit-content; margin: 0 auto;">Complete case report forms or electronic data capture</div> <p>↓</p> <div style="border: 1px solid black; background-color: yellow; padding: 5px; width: fit-content; margin: 0 auto;">File/route study visit documents</div> <p>↓</p> <p>To "Study Close-out" Phase</p> <p>↓</p>		
				<div style="border: 1px solid red; padding: 5px; display: inline-block;">See Level III map for details</div>	

# Clinical Trials Process Level II Map

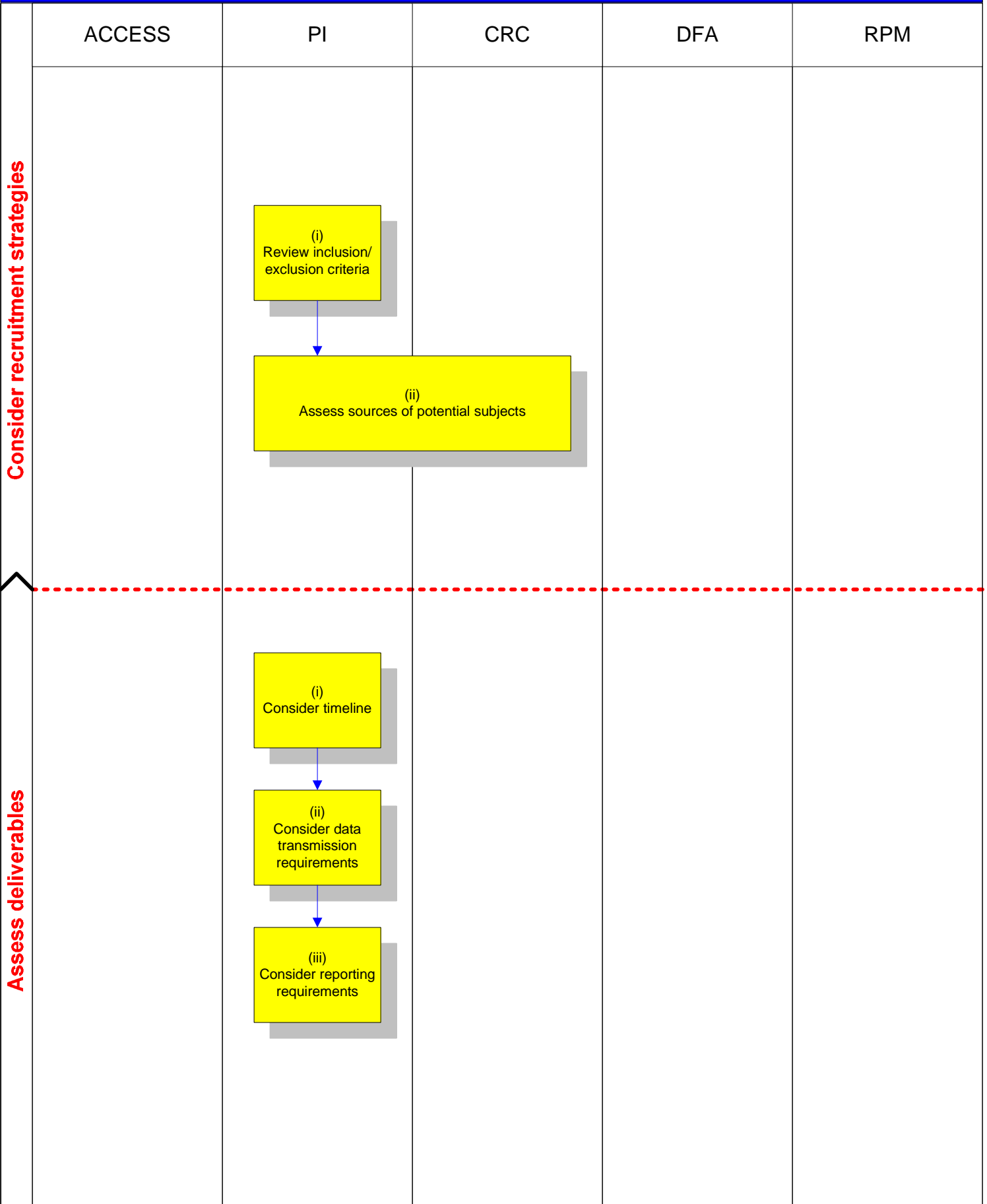
## Study Close-out Phase



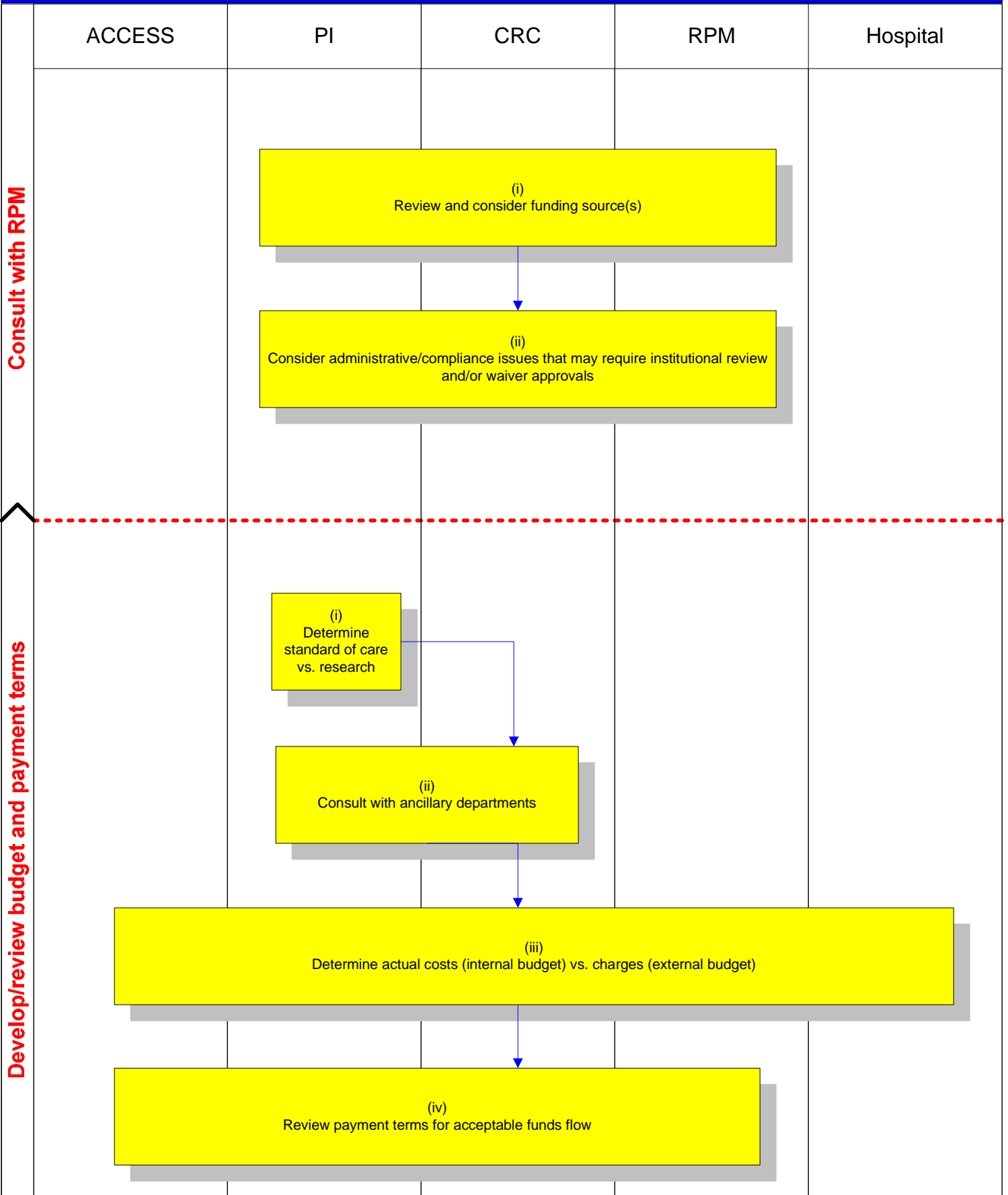
Develop or Receive Study Plan (from a sponsor) Phase

	ACCESS	PI	CRC	RPM	Hospital
Review study design		<pre>                     graph TD                         A["(i) Consider Biostatistical/ epidemiology design"] --&gt; B["(ii) Consider scientific/ professional merit and interest"]                     </pre>			

Pre-study Feasibility Assessment Process



Pre-study Start-Up Phase

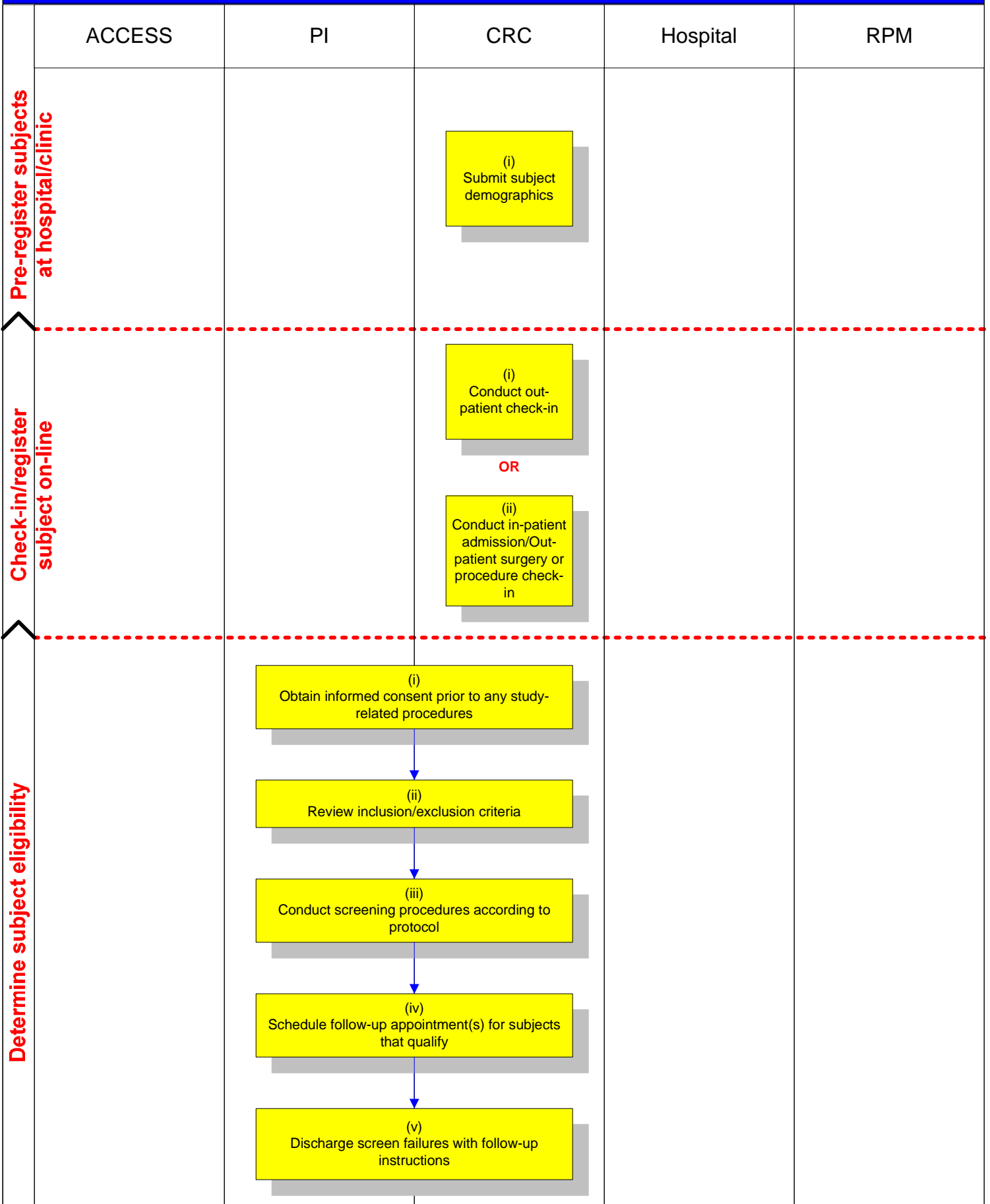


Study Start-up Phase

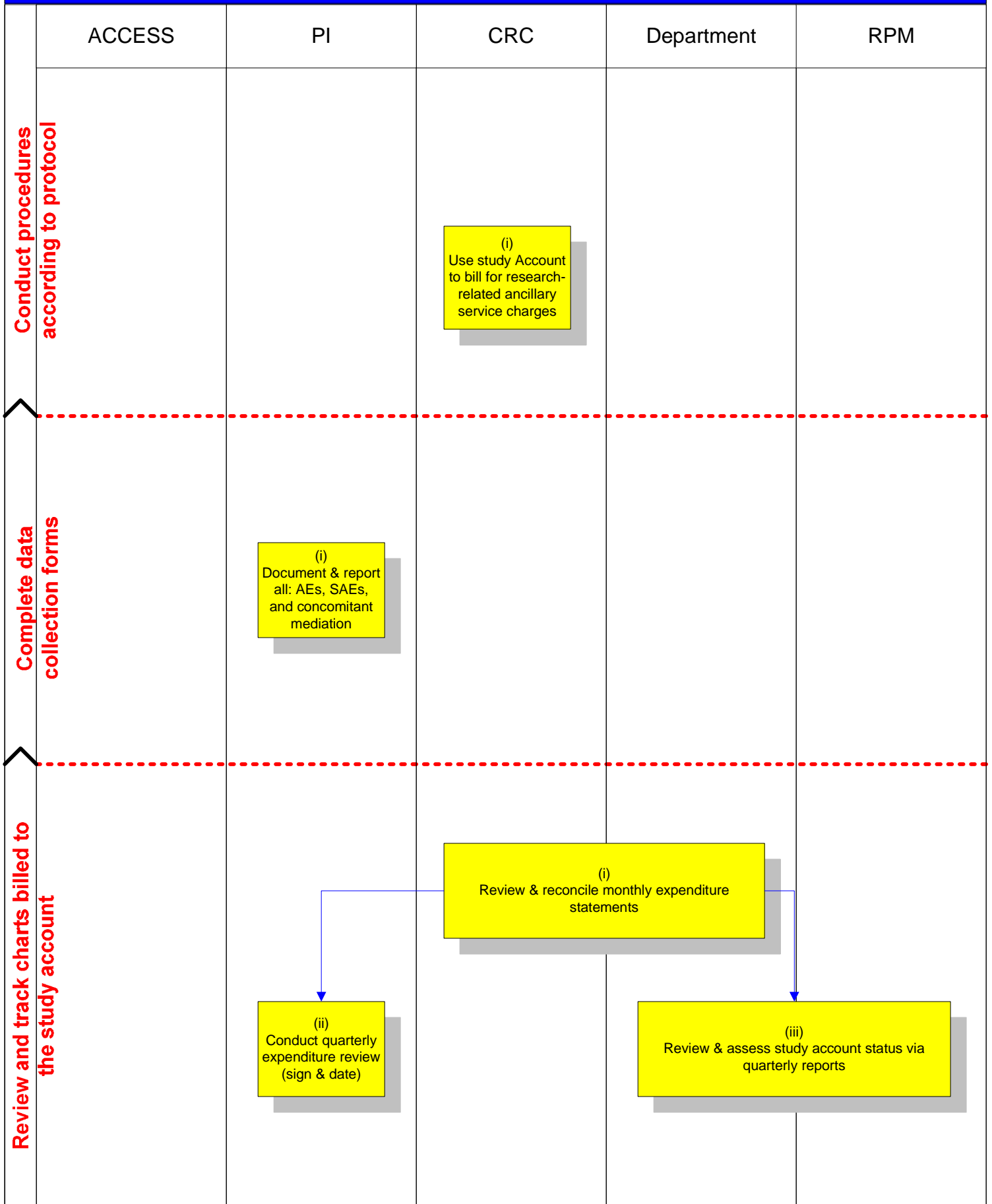
	ACCESS	PI	CRC	Hospital	RPM
Set-up research study account for billing patient hospital charges					

(i)  
Obtain gray study budget card from Admitting

Subject Screening Phase



Complete Subject Study Visits per Protocol



Complete Documentation of Study Visits Phase

	ACCESS	PI	CRC	Department	RPM
<p>Complete case report forms</p>			<pre> graph TD     A["(i) Complete informed consent forms"] --&gt; B["(ii) Complete progress notes"]     B --&gt; C["(iii) Complete lab reports"]     C --&gt; D["(iv) Complete doctor's orders"]     D --&gt; E["(v) Complete data collection forms"]     E --&gt; F["(vi) Complete medication administration forms"]     F --&gt; G["(vii) Complete tracking logs &amp; department study status reports"]     G --&gt; H["(viii) Complete correspondence"]     H --&gt; I["(ix) Miscellaneous"]                     </pre>		

Study Close-out Phase

