RUTGERS
THE STATE UNIVERSITY OF NEW JERSEY

Print Form

Rutgers, The State University of New Jersey

INSTITUTIONAL REVIEW BOARD (IRB)

FINAL STUDY REPORT/STUDY CLOSURE FORM APPENDIX 6

FOR MULTICENTER STUDIES

Clearly type all portions of this form.

FOR MULTICENTER STUDIES, PLEASE PROVIDE THE INFORMATION REQUESTED BELOW FOR EACH PERFORMANCE SITE.

PERFORMANCE SITE #1

4. 1 PARTICIPANT ENROLLMENT/CHARTS/RECORDS/SPECIMENS ANALYSIS INFORMATION

Complete the following for the study approved by a Rutgers IRB.

The number of participants is defined as the number of individuals who agreed to participate (i.e., those who provided consent or whose records were accessed, etc.) even if all did not complete the study.

a. The maximum number of participants approved by the IRB: _____

b. Total number of participants actually enrolled in the study: _____

c. Number of participants enrolled since last IRB review (initial or continuing): _____

d. If the total number of participants actually enrolled (b) is different from the maximum number of participants approved by the IRB (a), provide an explanation:

e. The number of individuals screened (those who signed consent, including screen failures): _____

f. The total number who actually completed the study: _____

g. The total number of dropped/withdrawn from the study: _____

Due to adverse events: _____

Other reasons: _____

(The total of f + g must = b)

CHARTS AND SPECIMENS

a. Number of specimens and/or charts approved by the IRB (This number can be found on your approval notices): _____

b. Did you review medical records, patient charts, radiographs or other patient information for this study? ☐ Yes ☐ No

Charts reviewed to date: _____

c. Did you analyze specimens (e.g. archival tissue, blood, blood products, or body fluids) for this study? ☐ Yes ☐ No

Specimens analyzed to date: _____

PERFORMANCE SITE #2

4. PARTICIPANT ENROLLMENT/CHARTS/RECORDS/SPECIMENS ANALYSIS INFORMATION

Complete the following for the study approved by a Rutgers IRB.

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f. The total number who actually completed the study: _____

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Due to adverse events: _____

Other reasons: _____

(The total of f + g must = b)

CHARTS AND SPECIMENS

a. Number of specimens and/or charts approved by the IRB (This number can be found on your approval notices): _____

b. Did you review medical records, patient charts, radiographs or other patient information for this study? ☐ Yes ☐ No

Charts reviewed to date: _____

c. Did you analyze specimens (e.g. archival tissue, blood, blood products, or body fluids) for this study? ☐ Yes ☐ No

Specimens analyzed to date: _____

PERFORMANCE SITE #3

4. 1 PARTICIPANT ENROLLMENT/CHARTS/RECORDS/SPECIMENS ANALYSIS INFORMATION

Complete the following for the study approved by a Rutgers IRB.

The number of participants is defined as the number of individuals who agreed to participate (i.e., those who provided consent or whose records were accessed, etc.) even if all did not complete the study.

a. The maximum number of participants approved by the IRB: _____

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d. If the total number of participants actually enrolled (b) is different from the maximum number of participants approved by the IRB (a), provide an explanation:

e. The number of individuals screened (those who signed consent, including screen failures): _____

f. The total number who actually completed the study: _____

g. The total number of dropped/withdrawn from the study: _____

Due to adverse events: _____

Other reasons: _____

(The total of f + g must = b)

CHARTS AND SPECIMENS

a. Number of specimens and/or charts approved by the IRB (This number can be found on your approval notices): _____

b. Did you review medical records, patient charts, radiographs or other patient information for this study? ☐ Yes ☐ No

Charts reviewed to date: _____

c. Did you analyze specimens (e.g. archival tissue, blood, blood products, or body fluids) for this study? ☐ Yes ☐ No

Specimens analyzed to date: _____