PORTEC-3 / CKTO 2006-04 SERIOUS ADVERSE EVENT FORM form 9, page 1 of 2

Please complete this form in case of a serious adverse event and ***fax at least page 1 within 24 hours*** *to:*
IKW Trial office, C7-143, LUMC, P.O. Box 9600, 2300 RC Leiden. Fax: 071-5266712

Institution number: |__|__|__| Patient study number: |__|__|__| Patient code: |__|__|__|

Contact physician, hospital and phone number: ……………………………………………………
……………………………………………………………………………………………………

New SAE report |__| (13) Additional information after previous SAE report |__| (14)

REPORT ON OCCURRENCE AND THERAPY OF SERIOUS ADVERSE EVENT

Date onset SAE: (dd/mm/yyyy) ……………..……… |__|__|.|__|__|.|2|0|__|__| (01)

Moment of SAE onset: 1 = on protocol treatment*, 2= off protocol treatment…………….. |__| (02)

* phase of protocol treatment: 1 = RT alone, 2 = concurrent phase, 3 = adjuvant phase …… |__| (03)

Treatment arm: 1 = RT alone, 2 = RT plus chemotherapy …………………………………… |__| (04)

Treatment according to protocol: 0 = no*, 1 = yes: ………………….……………... |__| (05)
* specify: ……………………………………..……………………………………

Action regarding protocol treatment: 0 = no, 1 = dose reduced, 2 = delayed, 3 = discontinued, 4 = other*
* specify: ……………………………………..……………………………………… |__| (06)

SAE category: …….……………………..…………………….…..……………….. |__| (07)
1 = death
2 = life threatening
3 = (prolongation of) hospitalization
4 = severe/permanent disability
5 = other, specify; …………

Causality from protocol treatment: …..……………………..…..…………………….. |__| (08)
0 = unrelated
1 = unlikely
2 = possible
3 = probable
4 = definite
5 = not evaluable, specify: ………………………………………………………….

Outcome of SAE: ………..…………………..……..…..…………………………….. |__| (09)
0 = resolved
1 = ongoing, recovering
2 = ongoing, recovery uncertain
3 = permanent disability
4 = deteriorating
5 = death

If resolved, date SAE resolved: (dd/mm/yyyy) ………. |__|__|.|__|__|.|2|0|__|__| (10)

If death, date of death: (dd/mm/yyyy) ……………………|__|__|.|__|__|.|2|0|__|__| (11)

cause of death: …………………………………………………….…………………………

CTC grade of SAE (***please also send in Form 6***): ………………………………….. |__| (12)

Short description of SAE: …………………………………………………………………………
……………………………………………………………………………………………………

Date: ....   *Name and signature: ....…………………….................*

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Institution number: |__|__|__| Patient study number: |__|__|__| Patient code: |__|__|__|

Contact physician and phone number: ……………..……………………………………….

Date onset of SAE:|__|__|.|__|__|.|2|0|__|__| Date initial report: |__|__|.|__|__|.|2|0|__|__|

Description of situation, treatment and other relevant information (such as relevant medical history and additional comments):

If not all items can be filled out at initial report, please fax additional information within 10 days

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Date: .... *Name and signature: ……………………………………………………….*