RTOG
Radiation Therapy
Oncology Group

Guidance for making changes to the RTOG informed consent template (revised 5/20/10):

RTOG prefers no changes be made to the model informed consent template other than to add local context but recognizes the IRB's right to request/require changes as outlined in the OPRR Report 93-01. The Deletion of any information should be avoided whenever possible to protect the patient and preserve the integrity of the document. This guidance was created to assist sites in making IRB requested/required changes appropriately.

Site IRBs can elect to:

- Add clarifying language or additional information to the RTOG model informed consent template as long as the essential elements/components remain intact.

This is acceptable without justification to the RTOG.

Site IRBs when utilizing their own consent templates <u>must include from the RTOG model informed consent template</u>:

- All portions related to correlative components. (see below for more detailed information)
- All information relating to risks and alternative procedures
- All essential elements/components as outlined in 21 CFR § 50.25.

The site IRB/Institution will therefore remain accountable for any changes made to the RTOG model informed consent.

When to notify RTOG?

Please notify the RTOG in writing if your site IRB requires a significant change from what is outlined above. This written justification must be in the form of a letter or can be a copy of the IRB minutes. You can mail or fax to us:

ATTENTION: REGULATORY/JUSTIFICATIONS & MODIFIED CONSENTS
RTOG Regulatory Affairs
1818 Market Street, Suite 1600
Philadelphia, PA 19103
Fax: 215-574-0300

Please note the RTOG Regulatory Compliance Department <u>does not review consents. All consent content will be reviewed at time of audit.</u>

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Correlative Components:

Institutional participation in an RTOG study requires that the site be prepared to participate/ have a plan in place to facilitate participation in all correlative components (e.g., QOL & tissue banking for future research and potential others) of the study. The site **must** offer each patient the opportunity to participate in all correlative components. **Only the patient** can choose to opt out of the correlative components of the study by declining during the consent process.

An Institutional IRB **cannot** elect to remove any portion of the consent related to correlative components.

Institutions should carefully review new clinical trials for all correlative components prior to making the decision to open the study at their sites.

Sites are compensated per specimen submission. The majority of RTOG studies require varying degrees of specimen collection as part of eligibility, stratification and/or protocol treatment. Sites are encouraged to coordinate tissue banking collections with protocol required specimen collections whenever possible.

In the event tissue is collected/residing at another facility RTOG expects a good faith effort to obtain the retrospective specimens but the site will not be penalized if it is not possible. This statement does not negate the requirement of being prepared to participate in all correlative components/having a plan in place to facilitate participation and offering the patient the opportunity to participate. Prospectively the site must inform the collecting entity that future specimens collected are expected to be forwarded along with the appropriate submission form for tissue banking as noted in the protocol.

PLEASE NOTE: If a site has removed the correlative components portion of the consent at an IRB's request using the IRB Justification of Consent Changes Process **the change is considered null and void and a major deficiency will be given during the site audit.**

Please also be advised, **there is no acceptable justification for the removal of the correlative components of the study**.

(*Page 3 which consists of internal procedures will not be included for external circulation)