PIVOTALboost Consent Form

REC ref: Patient Trial ID: ……………………………………..

**Please initial box**

**PART A**

***(Items 1-7 are required for your participation in PIVOTALboost)***

1. I confirm that I have read and understood the PIVOTALboost Information Sheet version 2 dated 5th June 2017 and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I agree to my name, date of birth, postcode, hospital number and NHS or Community Health Index (CHI) number being sent to The Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU) when I join PIVOTALboost.
4. I agree to ICR-CTSU using NHS and national electronic health and registration data to keep in touch with me and follow up my health.
5. I understand that sections of any of my medical notes may be looked at by responsible individuals from the research team, from regulatory authorities, from the Sponsor and their representatives, and by individuals from the participating NHS Trust where it is relevant to my taking part in the research. I give permission for these individuals to have access to my records.
6. I give permission for a copy of my radiotherapy treatment plan and associated treatment planning images (such as CT and MRI scans) to be sent to the Radiotherapy Quality Assurance team. I understand that this data will be anonymised prior to storage and may be used for future research in patients treated with radiotherapy.
7. I agree to my GP being informed about my participation in this study.
8. I agree to take part in the PIVOTALboost study

**Please initial box**

**PART B – OPTIONAL SECTION**

***Please initial to indicate whether you wish to consent to the following optional items.***

**No**

**Yes**

1. If I withdraw from the study, I consent to my doctor providing authorised researchers with basic clinical information that would be routinely collected and written in my medical records.

**Quality of Life**

1. I agree to take part in the PIVOTALboost Quality of Life Questionnaire Sub-Study.
2. I consent to researchers from The Institute of Cancer Research being sent my address and GP contact details.
3. I consent to researchers from The Institute of Cancer Research contacting my GP to confirm I am fit and well to receive questionnaire booklets to be sent out by post.
4. I consent to my GP disclosing my health status to researchers from The Institute of Cancer Research
5. I consent to researchers from The Institute of Cancer Research linking my NHS number to national databases in order to collect information relating to hospital visits and hospital activity.

**Tissue donation**

1. I consent to the donation of tissue from my diagnostic tumour sample as a gift for future research as described in information sheet.
2. I grant advance authorisation for possible future research on my stored samples, with the understanding that their confidential nature will be fully protected and that prior approval of an ethics committee will be obtained.
3. I agree that my tumour tissue samples can be analysed for potential changes in DNA (gene changes).

**Data sharing**

1. I grant advance authorisation for the possible future sharing of information collected, about me including any imaging (should I develop a recurrence of my cancer) with other organisations, with the understanding that I will not be identifiable from this information.

Name of Patient Date Signature

Researcher (PI) Date Signature

Name of person taking consent Date Signature

(if different from researcher)