 **Delete this line, then print first page of Information Sheet and Consent Form on Trust/Hospital headed paper**

**Bowel cancer patients with a ‘BRAFv600E’ genetic mutation:**

**Are ‘targeted drugs’ better than standard chemotherapy when given before surgery?**

**PATIENT INFORMATION AND INFORMED CONSENT FORM (PIS)**

(A large-print version of this form is available)

We invite you to take part in the international FOxTROT 4 research, part of the FOxTROT research programme. Before you decide, it is important that you know why we are doing the research and what is involved for you.

# **Why are we doing this research and why should I consider taking part?**

You have been diagnosed with stage 2 or stage 3 cancer of the bowel (colon) and your cancer has a particular genetic mutation called BRAF*V600E.*This genetic mutation can be the main cause for the cancer cells to grow, and current standard treatment options can be less successful in these circumstances. Your surgeon believes your tumour can be removed by an operation but there is always a risk that undetectable cancer cells may remain in your body resulting in your cancer ‘returning’.

There are two standard treatment approaches for your bowel cancer:

1. Traditionally, surgery is undertaken to remove the tumour(s) followed by, if necessary, a course of anti-cancer drugs (chemotherapy) to kill off any remaining but undetectable cancer cells.
2. An alternative to this is based on our international FOxTROT 1 research carried out in 2020, which showed that having some chemotherapy **before** surgery (called neoadjuvant chemotherapy), was better for patients.

The FOxTROT 4 research will test whether (or not) taking 2 ‘targeted’ drugs (called encorafenib and cetuximab) **before** surgery is even better for patients with a similar diagnosis to yours than the normal chemotherapy taken before surgery (as described in b above). A ‘targeted’ drug is one which targets and attacks specific genes and proteins that help cancer cells survive and grow. These targeted treatments have been shown to be effective for patients with BRAF*V600E* mutations where their bowel cancer has spread (stage 4 bowel cancer). This research aims to investigate if this treatment is effective for those patients with stage 2 and 3 disease.

If you have any questions please talk to <<Enter PI, nurse name >> at << Contact details for site>>