Schema Example: Trial with Screening Step and Multiple Treatment Steps

You agree to take part in this study and sign this consent form.

Your blood is tested to see if you have
EBV DNA.

If your blood does not have EBV DNA, you will not continue on the study. Your doctor will discuss other choices with you.

If your blood has EBV DNA, you will get the standard cisplatin and radiation treatment for about 6 weeks.

Your blood is tested again after the treatment. The results of the blood test decide which study group you will be placed in.

**Groups 1 and 2:** Patients who have EBV DNA in their blood

**Groups 3 and 4:** Patients who do not have EBV DNA in their blood

Randomize – The computer randomly puts you in a study group.

Randomize – The computer randomly puts you in a study group.

Long-Term Follow-Up

**Group 4:** No chemotherapy used. Doctors will check you on a regular basis.

**Group 1:** Treated with chemotherapy drugs cisplatin and
5-fluorouracil

**Group 3:** Treated with chemotherapy drugs cisplatin and 5-fluorouracil

**Group 2:** Treated with chemotherapy drugs gemcitabine and paclitaxel

Schema Example: Includes Screening Steps and Multiple Pathways to Study Arms

You agree to take part in this study and sign this consent form.

You have surgery to check for cancer in your Sentinel Lymph Nodes.

During surgery, if one or more Sentinel Lymph Nodes has cancer cells, you will be randomly put into a study group.

During surgery, if none of your Sentinel Lymph Nodes have cancer, you will not continue on the study. Your doctor will discuss other choices with you.

Doctors may need to do more tests after surgery to find out if you have cancer in your lymph nodes.

After these tests, you will not continue on the study. Your doctor will discuss other choices with you.

After these tests, if one or more Sentinel Lymph Nodes has cancer cells, you will be randomly put into a study group.

Randomize – The computer randomly puts you in a study group.

Long-Term Follow-Up

**Arm 1:** During the same surgery, more lymph nodes from your arm pit (called axillary lymph nodes) will be taken out.

You will begin standard radiation therapy 3 to 12 weeks after surgery.

**Arm 2:** During the same surgery, you will not have more lymph nodes removed.

You will begin standard radiation therapy 3 to 12 weeks after surgery.

Randomize – The computer randomly puts you in a study group.

**Arm 2:** You will not have another surgery to have more lymph nodes taken out.

You will begin standard radiation therapy 3 to 12 weeks after surgery.

**Arm 1:** You will have another surgery to take out more lymph nodes from your arm pit (called axillary lymph nodes).

You will begin standard radiation therapy 3 to 12 weeks after surgery.