**PACT Consent Checklist** – The Informed Consent forms for your trial must contain the following items:

* + Intellectual Property agreements for the trial proposed are compatible with PACT Policies
	+ Data Sharing consent is compatible with PACT Policies
	+ Data Sharing consent allows for the data to be banked in a controlled online repository for public access for broader research purposes by approved researchers
	+ Safety Event Reporting language assures that the proposed trial was conducted in a safe manner and all appropriate data has been reported to the appropriate regulatory agencies
	+ Sample Collection and Storage consent allows samples to be stored in an appropriately compliant biobank for PACT desired amount of time (recommendation would be at least 15 years)
	+ Sample/Biomarker Testing consent allows samples to be run on any assay
	+ Patients/samples are from the U.S. (currently a requirement until international data rules are dealt with appropriately)
	+ Consent details that no data from the additional biomarker testing will be returned to treating physicians, patients, or their families

**EXAMPLE DRAFT - Informed Consent Language for Prospective PACT Trials**

**PACT BIOMARKER TESTING**

You have been approached to take part in XXXX study and have indicated your agreement by signing a study level consent form. During your participation in XXXX study, we will be analyzing the samples you have provided to understand better the effect of study drugs and how patients respond to treatment as indicated in the main study informed consent. Some of these samples will be analyzed in laboratories taking part in PACT. Samples collected for this study defined biomarker testing may be stored for a period of up to 15 years after completion of the study, in order to allow for completion of the planned analyses. It is possible that, following completion of these analyses, some of your samples will still remain. These remaining samples will be destroyed after the above mentioned storage period.

We would like to invite you, through an additional consent, to consider contributing these remaining biological samples to a biobank. A biobank is a collection of samples of human bodily derived substances (e.g., organs, tissues, blood, cells, etc.) retained long term for open ended research purposes. Such research can help us further understand your disease or your response to the study treatments via tests other than those defined in the present protocol.

For example, if additional materials (e.g. tissue, blood, etc.) are available, they may be tested to explore additional biomarker data (genomic, transcriptomic, and proteomic) isolated and/or derived from your tumor. These tumor-specific analyses may help understand the characteristics of your tumor, in conjunction with a larger cancer patient population which the PACT partnership is assembling. Any subsequent analyses would not provide information on the likelihood of you or your relatives developing a disease.

If you agree, to any leftover specimen being used for this additional, undefined, exploratory biomarker testing, the leftover specimen may be stored in an appropriate repository designated by the Sponsor for a period of up to 15 years after completion of the final study report and may be used for further research. After that period, any sample remaining will be destroyed.

You will not be notified of the destruction or your samples. Nor will you be notified of any of the results of the research analysis performed on your samples, and these results will not be forwarded to your family or your doctor, neither stored in your medical records.

Your participation in this additional biomarker testing is voluntary. If you decide not to agree, this will not influence your participation in the main study and will not affect the quality of your care.

You can withdraw your consent from this contribution at any time. In this case, your remaining samples will be destroyed, but data already generated from your samples will be kept. Some of your health information, including but not limited to your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. Your study records will also be stored for future use. However, your name and other personal information will not be used.

To protect confidentiality of data, your samples will be labelled with a different ID than the study number and your subject number (Subject ID) so that your personal information (e.g., name, date of birth, etc.) cannot be linked back to the sample. All data will only be reported in coded form; confidentiality will be maintained, and your name will never be attached to those data. Some types of future research may include looking at your records and those of other patients to compare effects across many studies or comparing new study data with older study data. However, we don’t know what research may be done in the future using your information.

Your samples and data will be stored in appropriately secure conditions to control access and confidentiality. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.

Access to data collected from analysis of your samples or from clinical record will be restricted to people allowed by the PACT partnership, but this will eventually include appropriate public access by the research community. Under no circumstances will they know your identity, and all information will be treated as confidential. The PACT Partnership will use the NCI Cancer Moonshot℠ Public Access and Data Sharing Policy as the guiding principles for publication and data sharing. The full description of these policies can be found here: https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/funding/public-access-policy. These guidelines ensure your information can provide benefit to future researchers while maintaining your confidentiality.