Abbreviated Title: 18F-DCFPyL in HCC
NIH Protocol #: 000080
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NIH ADDENDUM

Title: ^{18}F-DCFPyL PET/CT in Hepatocellular Carcinoma

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Drug Name:	^{18}F-DCFPyL	^{18}F-FDG
IND Number:	133631	133631
Sponsor:	NCI CCR	NCI CCR
Manufacturer:	PET department, NIH	Commercial
Supplier:	PET department, NIH	MIB

Coordinating Center: NCI, CCR

TABLE OF CONTENTS

1 NUMBER OF PARTICIPANTS TO BE SEEN AT NIH

All 50 participants will be enrolled at the NIH. Some participants may have biopsies performed at the participating site.

2 NIH REGISTRATION INFORMATION

2.1 PARTICIPANT REGISTRATION AND STATUS UPDATE PROCEDURES

Registration and status updates (e.g., when a participant is taken off protocol therapy and when a participant is taken off-study) will take place per CCR SOP ADCR-2, CCR Participant Registration & Status Updates found at https://ccrod.cancer.gov/confluence/pages/viewpage.action?pageId=73203825.

2.2 COST AND COMPENSATION

2.2.1 Costs

2.2.2 NIH does not bill health insurance companies or participants for any research or related clinical care that participants receive at the NIH Clinical Center. If some tests and procedures are performed outside the NIH Clinical Center, participants may have to pay for these costs. Compensation

Please refer to section **3.8.2** of the main protocol.

2.2.3 Reimbursement

The NCI will cover the costs of some expenses associated with protocol participation. Some of these costs may be paid directly by the NIH and some may be reimbursed to the participant/guardian as appropriate. The amount and form of these payments are determined by the NCI Travel and Lodging Reimbursement Policy.

3 CORRELATIVE STUDIES FOR RESEARCH

3.1 SAMPLE STORAGE, TRACKING AND DISPOSITION

Samples will be ordered in CRIS and tracked through a Clinical Trial Data Management system. Should a CRIS screen not be available, the CRIS downtime procedures will be followed. Samples will not be sent outside NIH without appropriate approvals and/or agreements, if required.

3.1.1 Laboratory of Pathology

3.1.1.1 Clinical Tissue Samples

Tissues designated for clinical diagnostics are transported to the Laboratory of Pathology (LP) where they are examined grossly and relevant portions are fixed, embedded in paraffin and sectioned and stained for diagnostic interpretation. Unutilized excess tissue that is not placed in paraffin blocks is stored in formalin for up to three months, in accordance with College of American Pathologists/Joint Commission on Accreditation of Healthcare Organizations (CAP/JCAHO) guidelines, and then discarded. Following completion of the diagnostic workup, the slides and tissue blocks are stored indefinitely in the LP's clinical archives. All specimens are

catalogued and retrieved utilizing the clinical laboratory information systems, in accordance with CAP/JCAHO regulations. The use of any stored specimens for research purposes is only allowed when the appropriate IRB approval has been obtained. In some cases, this approval has been obtained via the original protocol on which the participant was enrolled.

3.1.1.2 Research Tissue and Blood Specimen (COMPASS Program)

All FFPE tissues that will undergo molecular pathology testing should be submitted through Surgical Pathology. Blood specimen should be delivered to room 3S247 in Building 10 (samples will be accepted from 7:30 AM to 4:30 PM Monday to Friday). Sample storage, tracking and disposition procedures will follow laboratory of pathology standard practice (section **3.1.1**).

3.1.2 Dr. Wang Laboratory

Surgical resected tumor tissue or needle biopsy core will be received after processing. Tumor tissue will be cut into small pieces and dissociated into single cells. For surgical resected tissue, part of tissue will be fixed for histological staining and excess tissue frozen down in liquid nitrogen. Each collection point may have multiple vials of cells frozen down, depending on the total number of cells. For those time points that have multiple vials of enough cells, different sequencing (e.g. single cell RNA-seq and ATAC-seq) could be done in parallel. The single cell and tissue storage will be recorded in Labmatrix. Records are updated upon sample disposition.

3.1.3 Dr. Jennifer Jones Laboratory

Serum and urine EVP samples will be stored in Dr. Figg's Biospecimen Processing Biorepository and will be analyzed in the Jones Laboratory. Samples will be processed in Building 10/B1B51/B1B53 and the LP COMPASS facility, with samples maintained during processing in rooms that are locked by badge access to only authorized personnel.

3.1.4 Blood Processing Core (Laboratory of Dr. William Figg)

3.1.4.1 Sample Collection

Remaining tissue samples will be obtained from the laboratory of pathology and stored in Dr. Figg's lab.

Please e-mail NCIBloodcore@mail.nih.gov at least 24 hours before transporting samples (the Friday before is preferred).

For sample pickup, page 102-11964.

For immediate help, call 240-760-6180 (main blood processing core number) or, if no answer, 240-760-6190 (main clinical pharmacology lab number).

For questions regarding sample processing, contact NCIBloodcore@mail.nih.gov

The samples will be processed, barcoded, and stored in Dr. Figg's lab until requested by the investigator.

3.1.4.2 Sample Data Collection

All samples sent to the Blood Processing Core (BPC) will be barcoded, with data entered and stored in Labmatrix utilized by the BPC. This is a secure program, with access to Labmatrix limited to defined Figg lab personnel, who are issued individual user accounts. Installation of

Labmatrix is limited to computers specified by Dr. Figg. These computers all have a password restricted login screen.

Labmatrix creates a unique barcode ID for every sample and sample box, which cannot be traced back to participants without Labmatrix access. The data recorded for each sample includes the patient ID, name, trial name/protocol number, time drawn, cycle time point, dose, material type, as well as box and freezer location. Participant demographics associated with the Clinical Center patient number are provided in the system. For each sample, there are notes associated with the processing method (delay in sample processing, storage conditions on the ward, etc.).

3.1.4.3 Sample Storage and Destruction

Barcoded samples are stored in barcoded boxes in a locked freezer at either -20 or -80°C according to stability requirements. These freezers are located onsite in the BPC and offsite at NCI Frederick Central Repository Services in Frederick, MD. Visitors to the laboratory are required to be accompanied by laboratory staff at all times.

Access to stored clinical samples is restricted. Samples will be stored until requested by a researcher named on the protocol. All requests are monitored and tracked in Labmatrix. All researchers are required to sign a form stating that the samples are only to be used for research purposes associated with this trial (as per the IRB approved protocol) and that any unused samples must be returned to the BPC. It is the responsibility of the NCI Principal Investigator to ensure that the samples requested are being used in a manner consistent with IRB approval.

Following completion of this study, samples will remain in storage as detailed above. Access to these samples will only be granted following IRB approval of an additional protocol, granting the rights to use the material.

If, at any time, a participant withdraws from the study and does not wish for their existing samples to be utilized, the individual must provide a written request. Following receipt of this request, the samples will be destroyed or returned to the participant, if so requested. The PI will record any loss or unanticipated destruction of samples as a deviation. Reporting will be per the requirements of section **7.2** of the main protocol.

Sample barcodes are linked to participant demographics and limited clinical information. This information will only be provided to investigators listed on this protocol, via registered use of the Labmatrix. It is critical that the sample remains linked to participant information such as race, age, dates of diagnosis and death, and histological information about the tumor, in order to correlate genotype with these variables.

3.1.5 CCR Sequencing Facility

RNA samples should be transported in dry ice. The names on the tubes are checked against the sample manifest and stored in a -80°C freezer. Sample data is entered in LIMS once samples have undergone a quality check (QC) according to established lab protocols. A sample QC report is generated and sent to the PI. LIMS labels are generated from the QC data and used to re-label the sample tubes. Once the QC is complete, samples are stored into the library construction box in the -80°C freezer.

The libraries are generated either manually or using automation following the established library prep protocol. Any leftover RNA is stored in the -80°C freezer. If the libraries pass QC, a

dilution of the library is passed on for qPCR and sequencing, and the library is stored along with the original RNA sample in the same box at -80°C. Each step is documented in a tracking sheet and LIMS.

The library dilutions are all stored at -30°C until sequencing is completed. Once the sequencing data is delivered, RNA samples and libraries are sent back to the PI.

4 NCI CLINICAL DIRECTOR REPORTING

Problems expeditiously reviewed by the OHSRP in the NIH eIRB system will also be reported to the NCI Clinical Director/designee; therefore, a separate submission for these reports is not necessary.

In addition to those reports, all deaths that occur within 30 days after receiving a research intervention should be reported via email unless they are due to progressive disease.

To report these deaths, please send an email describing the circumstances of the death to NCICCRQA@mail.nih.gov within one business day of learning of the death.

5 CONSENT DOCUMENTATION WHEN ELECTRONIC CONSENT DOCUMENT USED AT NIH

Manual (non-electronic) signature on electronic document:

When a manual signature on an electronic document is used for the documentation of consent at the NIH Clinical Center, this study will use the following to obtain the required signatures:

- Adobe platform (which is not 21 CFR Part 11 compliant); or,
- iMedConsent platform (which is 21 CFR Part 11 compliant)

During the consent process, participants and investigators will view individual copies of the approved consent document on screens at their respective locations (if remote consent); the same screen may be used when in the same location but is not required.

Both the investigator and the participant will sign the document using a finger, stylus or mouse.

Note: Refer to the CCR SOP PM-2, Obtaining and Documenting the Informed Consent Process for additional information (e.g., verification of participant identity when obtaining consent remotely) found at https://ccrod.cancer.gov/confluence/pages/viewpage.action?pageId=73203825.