This is the primer on data entry for the Neuro-Oncology Branch GBM Pembro HSPPC (17-C-0034) study.

### General Information

#### Useful site addresses

Labmatrix is a web-based application, and is accessible at the URL https://labmatrix.nci.nih.gov/labmatrix/. Your login credentials are your central NIH username and password.

Manuals for Labmatrix can be found at the bottom of the home page once you've logged in.

#### Labmatrix Lab Loader

If you are importing clinical labs or cultures, you'll also be using the Labmatrix Lab Loader web application, which lives at https://lmlabs.cancer.gov/; your account information is again the same as your NIH username and password.

#### Getting help

All assistance with Labmatrix and related tasks should be emailed to: ncilabmatrixhelp@mail.nih.gov.

We have a centralized support system for NCI's Labmatrix installation. Emailing your request means that it is automatically entered into our work tracking system, and doesn't linger in a specific user's inbox; we can also track our responses to issues, and collaborate within our own group in solving problems as they come up. So please submit all requests for assistance via this email address! It's available as a link from Labmatrix's help page, on the login page of Labmatrix, and as a link at the bottom right of the Labmatrix home page.

#### Separation of the Person and the Subject

A critical distinction to understand in Labmatrix is the distinction between a Person and a Subject, a distinction that reflects the difference...
between a human being’s properties (e.g., name, demographics) and the properties related to that human’s participation in a study (e.g., the start date of the participation, their custom ID on the study). The distinction allows Labmatrix to enforce access limitations so that study data is only visible to that study’s users, yet the general information about NIH patients is visible to the entire NIH community. Below is a simplified diagram showing the relationship of the two; the green area is the Person and associated data, and the yellow area is the Subject and associated data.

Person

The notion of a Person reflects the information which specifically describes a human being’s properties – things such as name, date of birth, gender, race, ethnicity, and medical record numbers. This is the part of the above diagram in the green box; you’ll note the small “Race” and “Medical Record Number” boxes, which indicate that a single Person might have more than one of these (e.g., multi-racial, or different MRNs at different institutions).

Subject

The notion of a Subject is what connects a Person to a study – e.g., the Person named “John Doe” is participating on a study named “Cancer Stem Cells”, so that Person has a Subject record which links him to the Study. The easiest way to remember this distinction is by remembering that any one human being can participate in more than one study – for example, the person John Doe might be participating in a Derm Branch study, a Radiation Oncology Branch study, and a Surgery Branch study.

There is still only one human being, so there’s only one Person record, but there are multiple Subject records linked to that Person which each represent the person enrolled on a specific study. The entire NCI can access that one Person record, but only those people with permissions to access each individual study can access each individual Subject record and the data that’s linked to it. (So in the above diagram, each yellow box represents a separate access group, and the data within each is only accessible to those users with the proper permissions on that study.)

In Labmatrix, if you’re viewing a Subject record, there will be a gray box near the top of the record with the information about the Person, and then a link within the record that lets you bring up the Person record itself. If you’re viewing a Person record, then there’s a tab that will list all the Subjects for that one Person.

Entering new subjects into Labmatrix

Because of the above distinction, when it’s time for you to enter a new subject into Labmatrix, that person might already be in Labmatrix (e.g., they’re participating in another study), or a colleague might have already entered their subject info for this specific protocol into Labmatrix.

In order to enter a new subject, click on the “Data Entry” menu at the top of the home page, and then use the “NIH Subject” menu item underneath “Create New”. The first step will ask you to enter an MRN, and then you should click “Search” to check to see if there’s an existing record for that MRN.

If there is an existing Person record: the record will be opened, with an alert message at the top reading “A single Person record has been found.” You should click on the “Subjects” tab to make sure that there isn’t already a subject record for this study. If there isn’t, just use the “Create New Subject” link a the top right of the record, enter the study name (GBM Pembro HSPPC), and click “Create Subject”.

If there is not an existing Person record: the NIH demographics database will be queried, and if the MRN matches a known patient, a new Person record will be created and opened (along with an alert that reads “A new Labmatrix Person record has been created from the NIH Registry”). Now, you can use the “Create New Subject” link at the top right of the record, enter the study name (GBM Pembro HSPPC), and click “Create Subject”.

Once you’re entering the new Subject record, you need to:

1. Enter the subject’s custom study ID into the Code field (note that this is critical, since Scribe uses the subject’s code to tie Scribe survey responses back to Labmatrix subject records).
2. Click on the Forms tab, then the Subject Protocols form in the left-hand column, and then the “Add Subject Protocols...” link near the top of the record; add a new record with the 17-C-0034 protocol along with the protocol start date.

Once you’re done entering the subject info, click the “Save” button at the top of the record to save it.

MDASI-BT data

The GBM Pembro HSPPC study is recording just the MDASI-BT data in Labmatrix. This form is accessible within a subject’s record; existing data is present in the “Forms” tab within that record, and entry of new data takes place via either Scribe or via the “Forms” tab.
Entering new MDASI data

In order to enter new information, you use the "MDASI-BT" form from the left-hand column of the "Forms" tab for the correct subject.

1. Search for and retrieve the relevant subject record so that it's open.
2. Click the "Forms" tab at the top of the record.
3. From the left-hand column listing of all the relevant custom data forms, choose the "MDASI-BT" form.
4. Click the "Add MDASI-BT..." link at the top of the record (below the tab bar), and enter the data.
5. Click the "Save" button at the top of the record when data entry is complete.

Viewing existing MDASI data

All existing data for subjects is visible within the "Forms" tab of the subject's record.

Scribe

Scribe is the system used to generate and administer survey sessions for subjects to fill out the MDASI-BT survey online (vs. on paper).

Logging into Scribe

Using any web browser, go to https://scribe.cancer.gov/. Your login is your NIH credentials. Once logged in, you will see a pull-down menu for selection of a survey realm; for this study, the survey realm is 17-C-0034 (GBM Pembro HSPPC).

Creating a new survey session

On the right hand page of the dashboard is the "Create new survey session" dialog box. There, fill in the subject's study participant ID (this is the exact custom ID you entered for them in Labmatrix above) and choose a timepoint on the study. If needed, fill in a comment about the timepoint, and then click the "generate survey session" button.
Once the survey session is generated, you will see a confirmation page. In the middle of the page is a green “Start the surveys now!” button; this is intended to be used if you are sitting with the subject and using a tablet or other device you intend to hand the subject for them to fill the survey out immediately. If this is the case, tap the button and hand the device to the subject.

Otherwise, there is a field at the bottom of the page containing the unique link for this new survey session; copy that link, and then send it to the subject however you might normally communicate with them.

**Viewing survey session information**

The dashboard shows you all currently-configured survey sessions for the study. By default, the table is sorted by study ID ascending and session creation date descending; you can click (and shift-click) on any of the column headers to re-sort the table, and you can use the “Search” field to immediately filter the table.

Each survey session has a blue “i” icon in the ID column; clicking on this gives you more information about that specific session, and gives you the link to the session.