Document Coversheet

Study Title: Piloting 'mPal,' a Multilevel Implementation Strategy to Integrate Non-hospice Palliative Care Into Advanced Stage Lung Cancer Treatment

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KEY INFORMATION FOR PILOTING 'mPal,' A SUPPORTIVE CARE TOOL FOR ADVANCED STAGE LUNG CANCER PATIENTS

We are asking you to choose whether or not to volunteer for a research study about a new tool, called mPal, which is designed to help educate lung cancer patients about a supportive care resource, identify care needs, and help communicate those needs to their cancer care team. We are asking you because you are 18 years of age or older and are receiving treatment for lung cancer at Markey Cancer Center. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn whether it is feasible to offer mPal as part of routine lung cancer care. If you agree to participate, you will be asked to complete brief surveys at three time points. You will also participate in one of two groups, Group A or Group B.

Group A will receive mPal. mPal consists of (1) ~5 minutes of educational content (video and text) describing a supportive care resource and (2) a screener that will determine your potential care needs (~5 minutes to complete). You may be asked to complete the ~5-minute screening tool at future oncology visits, but this will be no more than 3 times within the 3-months after you view the mPal education, unless you request to continue to take it. To effectively communicate your care needs to the cancer care team, a copy of care needs identified will be entered in your electronic health record for your cancer care team to view.

Group B will receive care as usual.

You will randomly be placed into Group A or B. Randomly placing people in two groups allows us to better examine the effects of the mPal tool. Group A participants will also answer a few questions about their experience with the mPal tool on their survey and complete interviews with the research team to provide feedback on its impact and what they liked/disliked about it. Overall, your participation in this research will span approximately 6-10 weeks from initial survey to follow-up survey and up to 3 months if you complete the care needs screener at future oncology visits. In total, your participation will take about two – two and a half hours total.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might volunteer to contribute to knowledge that could help other people going through lung cancer in the future.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

There is a potential risk of discomfort or distress when completing the questionnaires. You have the right to skip any questions and you may leave the study at any time without penalty. There is also a risk of loss of confidentiality, as identifying information will be collected in order to monitor your data throughout the course of the planned research. However, this is unlikely considering the careful plans in place regarding data management and protection. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Laurie McLouth, PhD of the University of Kentucky, Department of Behavioral Science at 859-562-2526.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You will not qualify for this study if you have unstable brain metastases (i.e., progressive neurological deficits, inadequately controlled seizures, or requiring escalating steroid doses); have a cognitive (i.e., dementia) or psychiatric condition (e.g., psychotic disorder) for which participating would be inappropriate; are receiving palliative care; or are unable to speak and read English.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at University of Kentucky Markey Cancer Center/UK Chandler Hospital during your normal clinic appointment with your oncology provider and/or remotely through Internet-based questionnaires. Viewing the mPal education will take ~5 minutes. Completing the mPal screener will take ~ 5 minutes. (Group A only). Completing surveys will take ~25 minutes. The interviews will take ~10 minutes (Group A only), and will be conducted either in-person, or via phone or teleconference, whichever is most convenient for you. The total amount of time you will be asked to volunteer for this study is approximately 2-2.5 hours over the next 6-10 weeks.

WHAT WILL YOU BE ASKED TO DO?

All participants:

All participants will complete three surveys that ask a variety of questions, including some about your knowledge of supportive care resources, quality of life, and demographic information. Two of the surveys will take approximately 25 minutes; one survey will take ~5-10 minutes to complete. Each can be done on paper, online using a computer or tablet, or over the phone. You will take this survey before you are assigned to a Group and ~4 and ~8 weeks later.

If you decide to participate, you will be randomly assigned to either Group A or Group B. Random assignment means that you are put into a group by chance (it's like flipping a coin). You have a one in two (50%) chance of being placed into either group. Group A will receive the mPal tool, while Group B will receive usual care.

Group A Only:

Group A participants will use the mPal educational tool once either in clinic using a tablet with study staff or at home using MyChart. mPal includes a brief educational video about a supportive care service, answering a few questions about care needs and whether they want to discuss those needs with their cancer care team. These needs will be entered in their electronic health record for their cancer care team to view. Group A participants may be asked to complete the ~5-minute care needs screener at future oncology visits, no more than 3 times within the 3 months following completing the mPal educational tool.

To get feedback on the mPal tool, Group A participants will be asked to complete a few additional survey items on their ~4-week follow-up survey about their experience with mPal, and a roughly ~10-minute interview with the study team to talk about what they liked/disliked about the tool. Approximately 4-weeks later, participants will complete a roughly ~10-minute interview with the study team to talk about how the mPal tool affected their cancer care. The interviews will be audio-recorded and transcribed into text using a confidential third-party transcription service (nVivo) and we will delete any identifying information from the transcripts. Once these transcripts have been written and analyzed, we will permanently delete all audio files from study computers and request permanent deletion at nVivo.

Group B Only:

Group B participants will receive care as usual.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

For all participants, there is the potential risk of discomfort or emotional distress when completing questionnaires. To protect against distress, you have the freedom to skip any questions in assessments that make you uncomfortable without penalty.

There is a risk of loss of confidentiality, as identifying information will be collected to monitor your data throughout the course of the planned research.

Unknown risks. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. Some people have benefited from learning about supportive care services and thinking about their care needs. This may be more likely for people in Group A. If you take part in this study, information learned may help others with your condition.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs to participate in this study.

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. During this study, we will collect your contact information to use for contacting you about the follow-up survey and/or interview. This identifying information will be kept separately from any and all data you provide us on surveys. This information is linked to your name by a study generated Study Identification number. Only the researchers will have access to the file linking your study ID with your name. Once data collection is complete, this key will be permanently deleted and all identifying information will be removed from records. The study staff will keep any paper copies of study files locked in a file cabinet in a private office. We will use your Study ID rather than your name on study records.

You should know that in some cases we may have to show your information to other people.

For example, the law may require or permit us to share your information with:

- a court or agencies, if you have a reportable disease/condition;
- authorities, such as child or adult protective services, if you report information about a child or elder being abused;
- authorities or a mental health professional if you pose a danger to yourself or someone else (e.g. suicidal thoughts).

To ensure the study is conducted properly, officials at the University of Kentucky and the National Institutes of Health (NIH) may look at or copy pertinent portions of records that identify you.

We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained by way of the Internet (e.g., any surveys completed online). Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of the University of Kentucky.

REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

Certificates of Confidentiality (CoC):

To help us protect your privacy, this research has a Certificate of Confidentiality. The researchers can use this Certificate to refuse to disclose information that may identify you to anyone not connected with this study, or in any legal proceedings. The exceptions to this rule are release of information:

- you have requested us to provide, for instance, to your insurance company or doctor;

- to the sponsor (e.g., National Institutes of Health) or agency auditing the research (e.g., Food and Drug Administration);
- about child or elder abuse, neglect, or harm to yourself or others; and
- about you if it involves a reportable disease.

This policy does not prevent you from releasing information about your own participation in this study. By signing this consent, you agree that your healthcare providers and associated staff affiliated, contracted with, or with access to records of the University of Kentucky (UK) may see your information from research studies and consider and use that information in the course of medical care and related activities.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study. If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

The study intervention will no longer be provided to you.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study, unless it focuses on a similar topic. It is important to let the investigator know if you are in another research study. You should discuss this with the investigator before you agree to participate in another research study while you are in this study. Participating in this research study would not interfere with cancer treatment studies you may be involved with.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

Throughout the study, you will receive gift cards on the following schedule:

- After baseline assessment (all participants): $20
- After the mid-assessment/~4 weeks after baseline (all participants): $10
- After the mid-assessment interview (Group A only): $10
- At an ~8-week follow-up assessment (all participants): $30
- After the follow-up assessment interview (Group A only): $10

TOTAL POSSIBLE: $80.00 (Group A); $60 (Group B)

With a few exceptions, study payments are considered taxable income reportable to the Internal Revenue Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to 1-2 times per year.

Do you give your permission to be contacted in the future by Laurie McLouth, PhD regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 80 people to do so at the University of Kentucky.

The National Institutes of Health is providing financial support for this study.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information collected in this study. This means that no link or code to your identity will be kept. After all identifiers have been removed, the information may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your de-identified information stored, they will be available indefinitely and cannot be removed due to the inability to identify them.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- age
- gender
- racial/ethnic data
- ZIP code
- lung cancer diagnosis (includes histology and stage)
- date started lung cancer treatment
- type of treatments received
- medical record number
- physician rated physical status (i.e., performance status)
- referrals for palliative care, palliative care consultations completed, referrals to other supportive care services (Social Work, Psycho-Oncology, Integrative Medicine, Hospice, Financial Services) and dates of referrals or completed visits
- care needs screening results from ongoing cancer treatment visits (Group A participants)
- Documentation of advance directive in medical record
- contact information (mailing address, email, phone – for payment purposes)

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives;
- Health systems outside of UK for which you have a patient relationship;
- National Institutes of Health

- Your primary oncology provider

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information may still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky;
- Current or future payments to the University of Kentucky;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- Send a written letter to: Laurie McLouth, PhD at 467 Healthy Kentucky Research Building, 760 Press Avenue, University of Kentucky, Lexington, KY 40536 to inform her of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

_____ **Signature of research subject**	_____ **Date**
_____ **Printed name of research subject**	
_____ Printed name of [authorized] person obtaining informed consent and HIPAA authorization	_____ Date