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Supplement 1: Cancer Eligibility Criteria – Patient's Cancer must fulfill either B or C

A	B	C
Laryngeal/Throat/Nasopharyngeal/Mouth a.k.a Head and Neck	Stage IV	"metastatic to", "refusing surgery/chemo", "not a surgical candidate" , recurrent, other (*specify___)*
Lung or Non-small cell lung cancer (NSCLC)	Stage IIIb Stage IV	"metastatic", "mets to", "refusing surgery/chemo" "malignant pleural effusion", "locally advanced" , recurrent, other (*specify___)*
Lung Small Cell	Extensive Stage	"metastatic", "mets to", "refusing chemo", recurrent, other (*specify___)*
Mesothelioma	Stage III Stage IV	"unresectable", "metastatic", "mets to", "refusing surgery/chemo" "not a surgical candidate, recurrent, other (*specify___)*
Breast	Stage IV	"metastatic", "mets to", "spread to" , other (*specify___)* AND "triple negative", "ER/PR negative", "hormone negative"
Esophageal	Stage III Stage IV	"metastatic", "mets to", spread to, recurrent "unresectable", "locally advanced", "not a surgical candidate" , other (*specify___)*
Stomach/Gastric	Stage III Stage IV	"metastatic", "mets to", spread to, recurrent "unresectable", "locally advanced", "not a surgical candidate" (exception for stage II gastric CA, not a surgical candidate is ELIGIBLE) , other (*specify___)*
Pancreatic	Stage III Stage IV	"metastatic", "mets to", spread to, recurrent "unresectable", "locally advanced", "not a surgical candidate" , other (*specify___)*
Gallbladder/Bile Duct/Cholangio/ Ampullary	Stage II Stage III Stage IV	"metastatic", "mets to", spread to, recurrent "unresectable", "locally advanced", "not a surgical candidate" , other (*specify___)*
Liver/Hepatic, Hepato-cellular (HCC)	Stage III Stage IV	"metastatic", "mets to", spread to, recurrent "unresectable", "locally advanced", "not a surgical candidate", "ineligible/not a transplant candidate", ascites, not a candidate for TACE, Y-90, local treatments, other (*specify___)*
Colon/Rectum/Colo-rectal	Stage IV Dukes D	"metastatic", "mets to", spread to, recurrent "unresectable", "locally advanced", AND "not a surgical candidate"; other (specify___)
Kidney/Renal Cell	Stage IV	"metastatic", "mets to", spread to, recurrent "unresectable", "not a surgical candidate" , other (specify___)
Ovarian	Stage IV	"metastatic", "mets to", spread to, recurrent "unresectable", "not a surgical candidate" , other (specify___)
Endometrial/Uterine	Stage IV	"metastatic", "mets to", spread to, recurrent "unresectable", "not a surgical candidate" , other (specify___)
Cervical	Stage IV	"metastatic", "mets to", spread to, recurrent "unresectable", "not a surgical candidate" , other (specify___)
Prostate	Stage IV	"metastatic", "mets to", spread to, recurrent, AND "hormone refractory" or "castration resistant"; other (specify___)
Melanoma	Stage IV	"metastatic", "mets to", spread to, recurrent, other (specify___)
Brain	N/A	Recurrent, relapsed, not a surgical candidate, mets to, refusing surgery/radiation, chemotherapy, other (specify___)
Anal	Stage IV	"metastatic", "mets to", spread to, recurrent "unresectable", "locally advanced", "not a surgical candidate" , other (specify___)
Thyroid (eligible papillary, follicular, medullary and all anaplastic)	Stage IV	Unresectable, metastatic, mets to, refusing chemo/surgery, not a surgical candidate, other (specify___)

Vulva	Stage IV	Unresectable, metastatic, mets to, refusing chemo/surgery, not a surgical candidate, other (specify___)
Penis	Stage IV	Unresectable, metastatic, mets to, refusing chemo/surgery, not a surgical candidate, other (specify___)
Sarcoma	Stage IV	Unresectable, metastatic, mets to, refusing chemo/surgery, not a surgical candidate, other (specify___)
Other Type that meets criteria from Column C	N/A	"metastatic", "mets to", spread to, recurrent "unresectable", "locally advanced", "spread to regional lymph node," "not a surgical candidate" , not a chemo candidate, not a transplant candidate, not a radiation candidate, relapsed, other (*specify___)*

NYU Langone MEDICAL CENTER

Research Subject Informed Consent Form

Title of Study:	Emergency Medicine Palliative Care Access (EMPallA) s17-01211
Principal Investigator:	Corita Grudzen, MD, MSHS, FACEP Department of Emergency Medicine NYU School of Medicine 462 First Avenue, Suite 345A New York, NY 10016 (212) 263-8050
Emergency Contact:	Jeanne Cho, MPH Program Manager (212) 263-1276 Jeanne.Cho@nyumc.org

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to compare the effectiveness of two models of palliative care: 1. nurse-led telephone management, and 2. ‘in-person’ outpatient management. Palliative care is medical and supportive care that specializes in pain and symptom management. For example, palliative care can help with any pain you may be having or any discomfort associated with your treatment. It can also help with symptoms such as nausea, vomiting, dizziness, weakness, diarrhea, or any general discomfort. This wouldn’t be instead of your regular medical care, but in addition to it. You are being asked in participate in a research study because you have advanced illness and require palliative care.

3. How long will I be in the study? How many other people will be in the study?

Participation in this study will not prolong your length of stay in the Emergency Department. We will conduct follow-up interviews with you after 12 weeks, 6 months, and 12 months from your enrollment in this study via telephone, regardless of the group you are placed in to receive palliative care.

A total of 1,350 patients with advanced illness and 675 of their caregivers will be enrolled in nine Emergency Departments across the country.

We will enroll a total of 450 patients and 225 caregivers at NYU Langone Medical Center, Bellevue Hospital Center, and NYU Langone Hospital - Brooklyn.

4. What will I be asked to do in the study?

If you agree to participate, we will ask you questions (survey) about your medical, physical, emotional, and social well-being, loneliness, and symptom burden, as well as basic demographic questions. It will be done while you are in the Emergency Department and may take about 20 minutes. The survey questions will be interrupted should you need attention by a healthcare provider or if you are in pain or any other distress. You also have the option of completing this survey over the phone after you leave the hospital.

We will then randomly place you to receive either nurse-led telephone palliative care, or outpatient palliative care for up to 6 months. Like a flip of a coin, you will have an equal chance of being placed in either group. If you are placed in the outpatient palliative care group, you will be asked to visit the palliative care facility monthly for 6 months after enrollment in this study. If you are placed in the nurse-led telephone care group, you will receive ongoing palliative care support from a registered nurse by telephone for 6 months. Your primary care physician and/or treating specialist(s) will be notified that you are participating in this study.

You are expected to complete follow-up surveys at 12 weeks, 6 months, and 12 months after enrollment in this study via telephone with the research team. These follow-up surveys will be completed in separate occasions from the palliative care you receive. These surveys will ask similar questions as the survey you completed in the beginning.

We will look in your medical chart to find information on Emergency Department revisits and hospital admissions.

5. What are the possible risks or discomforts?

Risk of Study

There is a risk that the confidentiality of your personal information will be compromised. In order to lower this risk, you will be identified by only a study number. All study-related information will be stored securely. Psychological risks and discomforts may arise from answering personal and sensitive questions. You can decline to answer any question, or skip questions you don’t want to answer. We will take all measures necessary to minimize these risks.

Other Risks

As with all research, this study may involve risks that are currently unforeseeable.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

You may experience improvement in symptoms and medical, physical, emotional, and social well-being. It is also possible that future patients with advanced illness may benefit from the findings in this study.

8. What other choices do I have if I do not participate?

Regardless whether or not you decide to participate in this study, your care will not be affected in any way. You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will I be paid for being in this study?

You will be given a $40 gift card upon completion first survey at enrollment. You will be given a $20gift card for each completed follow-up phone survey interview. If you complete all the study surveys (questionnaires), you will receive $100 total in gift cards.

If you are placed in the outpatient palliative care group that requires visits, we will pay you back for travel costs to and from the facility. Up to $25 for each visit will be repaid to you in the form of a gift card. You are expected to make monthly visits to the palliative care clinic for 6 months after your enrollment in this study. If you complete all the visits to the outpatient palliative care facility, you may receive up to a total of $150 for travel costs in gift cards.

10. Will I have to pay for anything?

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility. There is no additional cost to you for participation in this study.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator’s name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have been enrolled, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, or study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- The study sponsor, the principal investigator, or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits. Your decision will not affect your future relationship with NYU Langone Medical Center.

13. How will my information be protected?

NYU Langone Medical Center, which includes NYU Hospitals Center and NYU School of Medicine, is committed to protecting the privacy and confidentiality of your health information. We are asking for your permission to use and to disclose your health information in connection with this study. You have the right not to give us this permission, in which case you will not be able to participate in this study. If you do not give this permission, your treatment outside of this study, payment for your health care, and your health care benefits will not be affected.

What information about me may be used or shared with others?
The following information may be used or shared in connection with this research:

- Information in your medical record and research record, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

You have a right to access information in your medical record. In some cases when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Medical Center policies and applicable law.

Why is my information being used?
Your health information will be used by the research team and others involved in the study to conduct and oversee the study.

Who may use and share information about me?

The following individuals may use, share or receive your information for this research study:

- The Principal Investigator, study coordinators, other members of the research team, and personnel responsible for the support or oversight of the study.
- The study sponsor: Patient-Centered Outcomes Research Institute (PCORI)
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- H+H personnel responsible for the support or oversight of the study at Bellevue Hospital Center.
- Other study sites

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

14. Optional permission for future use

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. Such health information may include biological samples from the study. To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. _____ Subject Initials

15. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

16. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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 website site at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

- ☐ Subject making his/her own "X" above in the subject signature line
- ☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date

Approved For Period: 5/7/2018 - 9/4/2018

NYU Langone MEDICAL CENTER

Research Subject Informed Consent Form

Title of Study:	Emergency Medicine Palliative Care Access (EMPallA) s17-01211
Principal Investigator:	Corita Grudzen, MD, MSHS, FACEP Department of Emergency Medicine NYU School of Medicine 462 First Avenue, Suite 345A New York, NY 10016 (212) 263-8050
Emergency Contact:	Jeanne Cho, MPH Program Manager (212) 263-1276 Jeanne.Cho@nyumc.org

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

You are being asked in participate in a research study because you are caring for a person who has advanced and terminal illness. The purpose of this study is to compare the effectiveness of two distinct palliative care models that vary by provider type and mode of delivery: nurse-led telephonic case management and facilitated, outpatient palliative care. Palliative care is medical care that specializes in pain and symptom management. Palliative care is also referred to as supportive care. For example, palliative care can help with any pain the person may be having or any discomfort associated with treatment. It can also mean help with any nausea, vomiting, dizziness, weakness, diarrhea, or any general discomfort. This wouldn’t be instead of regular medical care, but in addition to it.

3. How long will I be in the study? How many other people will be in the study?

While in the Emergency Department (ED), the survey should take no more than 20 minutes to complete. Participation in this study will not prolong the length of stay in the ED. We will conduct follow-up interviews with you after 12 weeks, 6 months, and 12 months from your enrollment in this study via telephone.

A total of 1,350 patients with advanced cancer and end-stage organ failure and 675 of their caregivers will be enrolled in nine Emergency Departments across the country. We will enroll a total of 450 patients and 225 caregivers at NYU Langone Medical Center, Bellevue Hospital Center, and NYU Langone Hospital - Brooklyn.

4. What will I be asked to do in the study?

If you agree to participate, we will ask you questions (survey) about caregiving difficulties and challenges of providing care and bereavement support, as well as basic demographic questions. It will be done while you are present in the Emergency Department and may take about 15 minutes. You also have the option of completing this survey over the phone after you leave the hospital. You are expected to complete follow-up surveys at 12 weeks, 6 months, and 12 months after enrollment in this study via telephone with the research team. These surveys will ask similar questions as the survey at enrollment.

You may leave the study at any time. If you decide to stop participating in this study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with receiving healthcare at this institution.

5. What are the possible risks or discomforts?

Risk of Study

There is a risk that the confidentiality of your personal information will be compromised. In order to lower this risk, you will be identified by only a study number. All study-related information will be stored securely. Psychological risks and discomforts may arise from answering personal and sensitive questions. You can decline to answer any question, or skip questions you don't want to answer. We will take all measures necessary to minimize these risks.

Other Risks

As with all research, this study may involve risks that are currently unforeseeable despite adequate efforts to minimize all known risks.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

You may experience less psychosocial and physical strain and improvements in physical, emotional, and social well-being. It is also possible that future patients with advanced illness may benefit from the findings in this study.

8. What other choices do I have if I do not participate?

Regardless whether or not you decide to participate in this study, your relationship with NYU Langone Medical Center will not be affected in any way if you decide not to participate. You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will I be paid for being in this study?

You will be given a $40 gift card upon completion first survey at enrollment. You will be given a $20 gift card each completed follow-up survey interview. If you complete all the study surveys (questionnaires), you will receive $100 total in gift cards.

Caregivers will not receive costs for travel if they accompany the patient to the outpatient facility if the patient is placed in the facilitated, outpatient palliative care group.

10. Will I have to pay for anything?

You will not be charged any additional fees by participating in this study.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have been enrolled, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, or study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.

- The study sponsor, the principal investigator, or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits. Your decision will not affect your future relationship with NYU Langone Medical Center.

13. How will my information be protected?

NYU Langone Medical Center, which includes NYU Hospitals Center and NYU School of Medicine, is committed to protecting the privacy and confidentiality of your health information. We are asking for your permission to use and to disclose your health information in connection with this study. You have the right not to give us this permission, in which case you will not be able to participate in this study. If you do not give this permission, your treatment outside of this study, payment for your health care, and your health care benefits will not be affected.

What information about me may be used or shared with others?
The following information may be used or shared in connection with this research:

- Information in your medical record and research record, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

You have a right to access information in your medical record. In some cases when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Medical Center policies and applicable law.

Why is my information being used?
Your health information will be used by the research team and others involved in the study to conduct and oversee the study.

Who may use and share information about me?
The following individuals may use, share or receive your information for this research study:

- The Principal Investigator, study coordinators, other members of the research team, and personnel responsible for the support or oversight of the study.
- The study sponsor: Patient-Centered Outcomes Research Institute (PCORI)
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- H+H personnel responsible for the support or oversight of the study at Bellevue Hospital Center.
- Other study sites

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

How long may my information be used or shared?

Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

14. Optional permission for future use

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. Such health information may include biological samples from the study. To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. _____ Subject Initials

15. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

16. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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 website site at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

- ☐ Subject making his/her own "X" above in the subject signature line
- ☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date

Supplement 4: Independent Variables

Variable	Coding	Source	Time
Group Assignment	Nurse-led telephonic case management, specialty outpatient palliative care	Project Manager	Enrollment
Healthcare system/hospital-level variables			
Enrollment Site	Beaumont—Royal Oak, Beaumont—Troy, Bellevue Hospital Center, Brigham and Women's Hospital, NYU Langone Medical Center, NYU Hospital – Brooklyn, Ohio State University, University of Florida, Yale New Haven	Project Manager	Enrollment
Patient-level variables			
Age	Years	Patient Interview	Enrollment
Gender	Female, Male, Other	Patient Interview	Enrollment
Medical Insurance	Medicare, Medicaid, Private, Dual-eligible, Self-pay, Other	Patient Interview	Enrollment
Race/Ethnicity	American-Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, Hispanic, White, Multi-Race, Other	Patient Interview	Enrollment
Education	Highest grade or degree completed	Patient Interview	Enrollment
Household Income	$0–24,999, $25,000–49,999, $50,000–99,999, $100,000–149,999, $150,000–199,999, ≥$200,000	Patient Interview	Enrollment
Marital Status	Married, Never married, Widow/Widower, Separated, Divorced, Living with Partner	Patient Interview	Enrollment
Birth Country	US, Other	Patient Interview	Enrollment
Primary Language	English, Spanish, Other	Patient Interview	Enrollment
Religion	Do not practice/believe, Catholic, Hindu, Jewish, Muslim, Protestant, Buddhist, Other	Patient Interview	Enrollment
Residence	Apartment (with or without elevator), Private home (with or without stairs), Rehabilitation facility, Adult residence, Nursing home/Skilled nursing facility, Hospice, Chronic care hospital, Other	Patient Interview	Enrollment
Heart Failure Class	Self-Assigned NYHA Functional Classification[37]	Patient Interview	Enrollment
COPD Stage	Modified Medical Research Council (mMRC) Dyspnea Scale (if FEV_1 value is not documented in the EHR)	Patient Interview	Enrollment
Functional status	Palliative Performance Scale version 2 (PPSv2)[39]	Patient Interview	Enrollment
Caregiver-level variables			

Age	Years	Caregiver Interview	Enrollment
Gender	Female, Male, Other	Caregiver Interview	Enrollment
Race/Ethnicity	American-Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, Hispanic, White, Multi-Race, Other	Caregiver Interview	Enrollment
Education	Highest grade or degree completed	Caregiver Interview	Enrollment
Household Income	$0–24,999, $25,000–49,999, $50,000–99,999, $100,000–149,999, $150,000–199,999, ≥$200,000	Caregiver Interview	Enrollment
Religion	Do not practice/believe, Catholic, Hindu, Jewish, Muslim, Protestant, Buddhist, Other	Caregiver Interview	Enrollment
Patient Relationship	NAC/AARP Caregiving in the U.S. 2015 Survey[42] (Relative, Companion/partner, Non-relative, Other)	Caregiver Interview	Enrollment
Distance from Patient	NAC/AARP Caregiving in the U.S. 2015 Survey[42] (Same household, Within 20 minutes, 20 min–1 hour, 1–2 hours from your home, More than 2 hours)	Caregiver Interview	Enrollment
Frequency of visits to patient (if not in household)	NAC/AARP Caregiving in the U.S. 2015 Survey[42] (More than once a week, once a week, few times a week, once a month, few times a month, few times a year, less often)	Caregiver Interview	Enrollment

Supplement 5. Dependent Variables

Aim	Variable	Instrument/Coding	Source	Time
1	Patient Quality of Life	FACT-G[26]	Patient interview	0, 12 weeks, 6 months*, 12 months
2	ED Revisit	Count	Administrative claims and self-report[27]	Up to 12 months from enrollment
2	Inpatient Days	Count	Administrative claims and self-report[27]	Up to 12 months from enrollment
2	Hospice Use	Yes/No	Administrative claims and self-report[27]	Up to 12 months from enrollment
3	Loneliness	Three-Item Loneliness Scale[31]	Patient interview	0, 12 weeks 6 months*, 12 months
3	Symptom Burden	Edmonton Symptom Assessment Scale Revised (ESAS-r)[33]	Patient Interview	0, 12 weeks, 6 months*, 12 months
4	Caregiver Strain	Zarit Burden Interview (Zarit-12)[34]	Caregiver interview	0, 12 weeks; 6 months*, 12 months
4	Caregiver Quality of Life	Patient-Reported Outcome Measurement Information System (PROMIS-10)[35]	Caregiver interview	0, 12 weeks, 6 months*, 12 months
4	Bereavement	Texas Revised Inventory of Grief (TRIG)[36]	Caregiver interview	3 months post-patient death

*Primary and secondary outcomes to be measured as change in measures from baseline to 6 months for Aims 1, 3 and 4 (except bereavement).

Supplement 6: NYU IRB Approval Letter

NYU School of Medicine
NYU LANGONE MEDICAL CENTER

Office of Science and Research
Institutional Review Board
1 Park Ave.| 6th Floor, | New York, NY 10016

Approval of Submission September 5, 2017

Dear Corita Grudzen:

On 9/5/2017 1:44 PM EDT, the IRB reviewed the submission below: All conditions for approval were met on 9/5/2017.

principal investigator	Corita Grudzen
email	Corita.Grudzen@nyumc.org
study number	i17-01211
study title	Emergency Department-Initiated Palliative Care in Older Adults with Advanced Illness
performance period	9/5/2017 - to 9/4/2018 inclusive. Before 9/4/2018 or within 30 days of study closure, whichever is earlier, you are to submit a continuing review with required explanations. You can submit a continuing review by navigating to the active study and clicking Create Modification / CR. If continuing review approval is not granted before the expiration date of 9/4/2018, approval of this study expires on that date.
location(s)	Bellevue Hospital (Bellevue), NYU Lutheran Medical Center (NYUMC Locations), Tisch Hospital (NYUMC Locations)
sponsor(s)	Name: PCORI;
review type	Initial Study, Expedited Cat 5, 7
board name	Reported to all boards
materials approved for use	• PCORI_WaiverofAuthorization_8.29.17.pdf, Category: Consent Form; • PCORI_CaregiverICF_8.17.17.pdf, Category: Consent Form; • PCORI_PatientICF_8.28.17.pdf, Category: Consent Form; • PCORI-IRB-Protocol_8.24.17_v1.pdf, Category: IRB Protocol; • CaregiverSurvey_Baseline_PCORI.pdf, Category: IRB Protocol; • PatientSurvey_Baseline_PCORI.pdf, Category: IRB Protocol; • CaregiverSurvey_FollowUp_PCORI.pdf, Category: IRB Protocol; • PatientSurvey_FollowUp_PCORI.pdf, Category: IRB Protocol; • PCORI_Email_to_Providers_08.29.17_v1.0.pdf, Category: Recruitment Materials
#of subjects approved to consent	675
vulnerable populations approved for participation in this study	

No human subject research activities at external participating sites can occur until after each local IRB approval is obtained and forwarded to the NYU SoM IRB via modification to be placed on the record.

The current IRB Status of your study is: Approved. This study was reviewed by the NYU School of Medicine's Institutional Review Board (IRB). During the review of your study, the IRB specifically considered:

1. the risks and anticipated benefits (if any) to your subjects
2. the selection of subjects
3. the procedures for securing and documenting informed consent
4. the safety of your subjects
5. the privacy of your subjects and confidentiality of the data

Your study cannot commence until all ancillary review decisions are complete. In order to determine the state of all ancillary reviews please go the My Studies page of this study in Research Navigator. Ancillary review statuses will be found on the right side of the header section.

Please note; if your study includes a clinical trial agreement or budget you will need to ensure approval has been issued from My Agreements/CRMS and The Office of Clinical Trials before you proceed with any aspects of this study including the enrollment of human subjects.

Review Notes

For NIH Grant funded research: the IRB has found the IRB approved protocol referenced above to be consistent with the NIH grant application.

Helen Panageas September 5, 2017

RE: Study#i17-01211

Helen Panageas, Director, Institutional Review Board OHRP #FWA00004952

Notes

- You must submit all changes to this study (e.g., protocol, recruitment materials, consent forms, etc.) via eSubmission to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB within 24 hours.
- You must report all adverse and/or unanticipated event(s) that occur during the course of this study to IRB via eSubmission in accordance with IRB Policy.
- Use only IRB-approved copies of your consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your study. Do not use expired consent forms.
- You must inform all research staff listed on this study of changes or adverse events that occur.
- IRB's approval is valid until the end date of the performance period indicated above. A reminder for renewal should be e-mailed to you from the IRB 90, 60 and 30 days before this study's approval is scheduled to expire. However, you are responsible for submitting all renewal materials at least eight weeks before expiration regardless of whether or not you receive a reminder notice.
- All IRB policy documents can be found on our website: http://irb.med.nyu.edu/library
- Prior to initiating an IRB-approved study, you must receive written approval from an authorized representative for each site where your study will take place. Key contacts are:
    - **Bellevue Hospital**: when Bellevue Hospital is listed as a site where your study can take place, please note that you may have to complete additional work in BHC's Reason system. Bellevue will be contacting you with any additional needed information. For questions on Bellevue Hospital research, please contact *BellevueResearch@bellevue.nychhc.org*
    - CTSI - Clinical and Translational Science Institute, NYU School of Medicine [formerly General Clinical Research Center (GCRC)], ctsi@nyumc.org.
    - NYU Langone Medical Center (Tisch Hospital/Rusk Institute/Co-op Care/HJD/Perlmutter Cancer Center) site approval is handled for you automatically (as needed) by the Office of Clinical Trials
- The IRB may terminate studies that are not in compliance with NYU Langone Medical Center/School of Medicine Policies & Procedures and the requirements of the Institution's Federal Wide Assurance with the Federal Government. Direct IRB questions, correspondence and forms (e.g., continuing reviews, amendments, adverse events, etc.) to 212-263-4110 or IRB-INFO@nyumc.org.
- Prior to initiating an IRB-approved study, you must receive written approval from an authorized representative of the Office of Clinical Trials. You may contact the Office of Clinical Trials at 212.263.4210 or clinicaltrials@nyumc.org.

NYU SoM IRB operates in accordance with Good Clinical Practices (GCP) and applicable laws and regulations. The NYU SoM IRB Federal Wide Assurance number is 00004952.