NCORP Program Planning Worksheet

Baseline Criteria for Eligibility

Version: 5.10.12

Level 1 Baseline Participation

Level 1 Baseline Participation

Criteria	Level 1: Baseline Participation
Criteria	Potential number of sites = ?? Potential award amounts ??
Delivery System/Organizational Requirements	
Minimum # of new analytic cancer cases	400
Sites Co-investment to public-private partnership	Yes. Quantification of co-investment (Includes in kind contributions) to ensure support for program requirements.
Senior leadership support	Yes. Written confirmation from institutions' research official supporting each of the program requirements.
Delivery System Attributes	Access to multidisciplinary/multispeciality teams to support multimodal clinical studies.
Linkage to community resources to facilitate research	Provide a plan for assessment of cancer care referrals to your program.
Disparities	
All patients screened offered treatment	Commitment to provide access to treatment to all screened regardless of insurance status during the funding period.
Community engagement, outreach and education	Identify at least one group (underserved population) to which cancer disparities and/or service efforts will focus. A plan to incorporate cultural competence training into staff orientation. A plan to educate patients and families about clinical trials. A commitment to establish linkages with NCI, Center to Reduce Cancer Health Disparities (CRCHD) other outreach networks to facilitate access to tailored and culturally-appropriate cancer education, via webinars or local/regional programs, for biospecimen collection and clinical trials.
Community partnerships	A plan to establish at least one collaborative community partnership to targeted underserved population and to support underserved accrual to clinical trials.
OMB Race & Ethnicity categories used	Required for clinical trials. Must have a system for tracking race and ethnicity for research activities connected to program goals.
Navigation	A lay health navigator/community health educator or its equivalence to enhance awareness of and access to clinical services.

Criteria	Level 1: Baseline Participation
Clinical Trials (DCP and DCTD)	
# of NCI Accruals	25
Type of trials	Participate in most common cancer multi-modality treatment trials; epidemiology or case-control studies.
Phase of trials	Phase III
Cooperative Group Membership	Member or affiliate of one NCI Cooperative Group, or member or affiliate of a CCOP/MB-CCOP
Research Resources	Clinical Research Nurse Data manager
Capacity to collect high quality biospecimens with related annotated data	Capacity for annotated biospecimen collection and handling paraffin embedded specimens
Systems for tracking/managing clinical trials	Yes. Description of tracking system required
Quality of Care (includes Survivorship, Palliative Care, Psychosocial, End of Life Care)	
Commission on Cancer Accreditation	No
Disease-specific Multidisciplinary Clinics (MDCs)	Experience in coordinating multiple disciplines in support of initiating clinical research. Plan to develop prospective multi-modality treatment planning teams with research nurse in attendance.
National Quality Reporting Initiatives • **Quality Oncology Practice Initiative (QOPI)**	Plan to develop capacity to begin QOPI participation.
Genetics as part of care model	Established referral system for genetic testing and counseling. Physicians and other providers routinely screening patients to identify eligibility for genetic counseling.
Care Coordination	Access to coordination services which encompass at least one disease site – routine screening for trial eligibility.
Relationship with *oncology* providers to facilitate participation in non-clinical trial research	Commitment of oncology providers to support clinical trial accrual and other Level I goals/initiatives.
Relationship with primary care providers (PCPs)	Identify primary care partners.
Survivorship, Palliative and Hospice Care	
Palliative care and hospice resources	Access (either via referral or on-site) within their community for palliative care and hospice referrals.
Psychosocial care resources	Access (either via referral or on-site) within their community to provide psychosocial support for patient.s
Psychosocial care delivery	Assessment of current psychosocial screening program for patients and provision of access (either via referral or on-

Criteria	Level 1: Baseline Participation
	site) to provide resources for and manage patients/family with psychosocial needs.
Tobacco Use	Commitment to assess all patients and family members for smoking/tobacco use status and referral for cessation.
End of life care	Commitment to provide end of life care based on patient preferences and evidence-based guidelines.
Research Infrastructure for broad research agenda	
IRB	Yes. Central IRB where applicable.
Linkages with Research Organizations	Clinical trial groups only.
Clinical Research Nurses	Yes. Experienced in clinical trials with capability to support other developmental studies based on convenience samples.
Electronic data linkages with NCI Research Effort (CDMS/CTMS)	Actively submitting all Cooperative Group data utilizing the new data submission web-portal.
Data retrieval capabilities	Basic medical record data extraction (electronically or manually) and case ascertainment methods to support studies using convenience samples.
Network participation **-ability to do cross-site data collection and research**	No

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Baseline Criteria for Eligibility

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Level 2: Intermediate Level Participation

Level 2: Intermediate Level Participation

Criteria	Level 2: Intermediate level Participation
Criteria	Potential number of sites = ?? Potential award amounts ??
Delivery System/Organizational Requirements	
Minimum # of new analytic cancer cases	1000
Sites Co-investment to public-private partnership	Yes. Quantification of co-investment (includes in kind contributions) to ensure support for program requirements.
Senior Leadership support	Yes. Written confirmation from institutions' research official supporting each of the program requirements.
Delivery System Attributes	Ability to produce evidence of successfully integrating multiple specialties within a cancer research program.
Linkage to community resources to facilitate research	Established relationships, based on an assessment of the specific needs of the community, to support the care of cancer patients, accruals to clinical trials and research projects with a particular focus on disparities.
Disparities	
All patients screened offered treatment	Commitment to provide access to treatment to all screened regardless of insurance status during the funding period.
Community engagement, outreach and education	Considering the specific needs within the community served, provide a plan to educate and engage community and partners (focus on clinical trials, biospecimen collections, and cancer prevention, treatment and screening) using at least one locality-specific approach in one cancer disease site.
Community partnerships	At least one partnership in place focused on engaging targeted underserved population for input on cultural values, norms, and language differences. Plans for at least one research initiative involving a community partner.
OMB categories used	Must have a system for tracking race and ethnicity for all site sponsored activities related to program goals including clinical trials, cancer patient registration, community screening programs.
Navigation	Access to at least one patient navigator with a focus on underserved populations.
Research Collaborations with Disparities Research Programs	Commitment to develop disparities research collaborations with NCI, Center to Reduce Cancer Health Disparities (CRCHD) or other disparities research programs and collaboratives.
Clinical Trials (DCP and DCTD)	
# of NCI Accruals	50 (combined cancer control and treatment)
Type of trials	Capacity for highly annotated biospecimens collection and reporting. Recruitment of cancer control/prevention and treatment trials.

Criteria	Level 2: Intermediate level Participation
Phase of trials	Phase II and III
Cooperative Group Membership	More than one NCI Cooperative Group membership.
Research Resources	Clinical Research Nurse Clinical Research Pharmacist Regulatory staff
Capacity to collect high quality biospecimens with related annotated data	Yes
Systems for tracking/managing clinical trials	Yes. Description of tracking system required.
Quality of Care (includes Survivorship, Palliative Care, Psychosocial, End of Life Care)	
Commission on Cancer Accreditation	Yes
Disease-specific Multidisciplinary Clinics (MDCs)	Experience delivering prospective multi-modality treatment with multidisciplinary planning teams (one disease site).
National Quality Reporting Initiatives • **Rapid Quality Reporting System (RQRS)** • **Quality Oncology Practice Initiative (QOPI)**	Participation in RQRS or another rapid quality reporting equivalent and signed data sharing agreement (NCI or NCORP). Participation in QOPI (At least one practice; twice annually) and signed data sharing agreement (NCI or NCORP).
Genetics as part of care model	Established referral system for genetics testing and counseling services on-site or via arrangements for breast and colon cancer. Physicians and other providers routinely screening patients to identify those eligible for genetic counseling.
Oncology specific EHRs	Plans for developing oncology specific EHR.
Care Coordination	Care Coordination services available for 1 disease site.
Relationship with *oncology* providers to facilitate participation in non-clinical trial research	Physician agreement to participate in quality improvement or other relevant research initiative agreed upon by the NCORP.
Relationship with primary care providers (PCPs)	Expand focus to include MD's for cancer control/prevention research.
Partnerships/collaborations with national organizations	Commission on Cancer or ASCO/QOPI as applicable

Criteria	Level 2: Intermediate level Participation
Survivorship, Palliative and Hospice Care	
Post-treatment care planning	Treatment summaries across all specialties delivered to >40% of patients within one disease. (Example: breast cancer)
Palliative care and hospice resources	Established routine access to palliative care and hospice services in the community.
Psychosocial care resources	Established access to a full-time mental health professional for consultation /research.
Psychosocial care delivery	Psychosocial screening >50% of patients within one disease site. Systematic access to in-house or referral resources to manage psychosocial care.
Tobacco Use	Assessment of patients and families for smoking/tobacco use status. Referral for smoking cessation provided.
End of life care	Plan for providing end of life care which incorporates patient preferences and evidenced-based guidelines, as well as staff education.
Research Infrastructure for broad research agenda	
IRB	Yes. Central IRB where applicable.
Linkages with Research Organizations	Clinical trials research organizations and other organizations which conduct non-clinical trial research.
Clinical Research Nurses	Clinical Research Nurse, Clinical Research Associate (CRA) or data management specialist that can support HSR, behavioral and outcomes studies.
Electronic data linkages with NCI Research Effort (CDMS/CTMS)	Developing the potential to link via EHR. Actively submitting all Cooperative Group data utilizing the new data submission web-portal.
Capacity to participate in CER	Yes (effectiveness studies only)
Dissemination and Implementation Research	Clinical Research Nurse, Clinical Research Associate (CRA) , or data management specialist with expertise in the sites data systems and organization of clinical care delivery
Data capabilities	Good quality control and data sharing protocols/ experience.
Network participation **-ability to do cross-site data collection and research**	Yes. Participate in network data harmonization on clinical data.

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Level 3: Advanced Level Participation

Level 3: Advanced Level Participation

Criteria	Level 3: Advanced Level Participation
Criteria	Potential number of sites = ?? Potential award amounts ??
Delivery System/Organizational Requirements	
Minimum # of new analytic cancer cases	1500
Sites Co-investment to public-private partnership	Yes. Quantification of co-investment (Includes in kind contributions) to ensure support for program requirements.
Senior Leadership support	Yes. Written confirmation from institutions' research official supporting each of the program requirements.
Delivery System Attributes	Ability to produce evidence of successfully integrating multiple specialties across clinical and non-clinical research programs.
Linkage to community resources to facilitate research	Provide examples of community organizations participation in research studies within your program.
Disparities	
All patients screened offered treatment	Commitment to provide access to treatment for all screened regardless of insurance status during the funding period.
Community engagement, outreach and education	A community outreach program with a track record of specific initiatives that engage the community/partners and using at least one locality-specific approach in a cancer program targeting a specific underserved population. Evidence of collaboration with researchers participating in cancer disparities in >1 phase of the cancer care continuum.
Community partnerships	Multiple community partnerships with at least one being formal (i.e. Memorandum of Understanding) – all with focus on providing access to the targeted population.
OMB categories used	Must have a system for tracking race and ethnicity for all site sponsored activities related to program goals including clinical trials, cancer patient registration, community screening programs. Capacity for tracking underserved cancer survivors.
Navigation	Site has navigation/service coordination tailored to specific ethnic patient population, disease site, and clinical trials. Site has capacity to participate in navigation research projects targeted to disparities program goals.
Research Collaborations with Disparities Research Programs	Capacity to perform evidence-based disparities intervention research that can increase the use of and access to beneficial biomedical procedures as well as enhance research participation and/or improve patient outcomes. Participation in complex cancer disparities research (Comparative effective research (CER), clinical trials retention, outcomes research).

Criteria	Level 3: Advanced Level Participation
Clinical Trials (DCP and DCTD)	
# of NCI Accruals	100 (combined treatment and cancer control)
Phase of trials	Phase II and III and capacity to perform phase I
Cooperative Group Membership	Participation in NCI or Cooperative Group activities; Non-clinical trial ancillary studies.
Research Resources	Clinical Research Nurse; Clinical manager Clinical Research Pharmacist with oncology focus (Required for Phase I trials)
Capacity to collect high quality biospecimens with related annotated data	Yes
Systems for tracking/managing clinical trials	Yes. Description of tracking system required.
Quality of Care (includes Survivorship, Palliative Care, Psychosocial, End of Life Care)	
Commission on Cancer Accreditation	Yes
Disease-specific Multidisciplinary Clinics (MDCs)	Provide outcome and prospective multidisciplinary treatment planning and delivery that includes primary care providers. (2 disease sites)
National Quality Reporting Initiatives • **Rapid Quality Reporting System (RQRS)** • **Quality Oncology Practice Initiative (QOPI)**	Participation in RQRS or another rapid quality reporting equivalent that incorporates outcomes of care (e.g., survival, PROs) for at least 2 disease sites. QOPI certified site.
Genetics as part of care model	Established referral system for genetics testing and counseling services on-site or via arrangements for breast and colon cancer. Physicians and other providers routinely screening patients to identify those eligible for genetic counseling. Capacity to participate in research studies focusing on genetics (examples: implementation of genetics guidelines in the community setting).
Oncology specific EHRs	Plans for developing oncology specific EHR.
Care Coordination	Integration of major primary care practices into care coordination efforts.
Relationship with *oncology* providers to facilitate participation in non-clinical trial research	Physician agreement to participate in quality improvement or other relevant research initiative agreed upon by the NCORP.
Relationship with primary care	The cancer program has alignment with the major primary care practices in the community to support program goals

Criteria	Level 3: Advanced Level Participation
providers (PCPs)	and an expanded research agenda that includes primary care cancer- related research questions.
Partnerships/collaborations with national organizations	University-based research institutions, NCI Cancer Centers, other types of research organizations.
Survivorship, Palliative and Hospice Care	
Post-treatment care planning	Treatment summaries delivered to >40% of patients within 2 disease sites.
Palliative care and hospice resources	Established routine access to palliative care and hospice services in the community.
Psychosocial care resources	Recognition of the importance of psychosocial care for patients. Established access to a part or full-time senior (experienced, not newly credentialed) mental health professional for consultation /research.
Psychosocial care delivery	Psychosocial screening >50% of patients within one disease site. Systematic access to in-house or referral resources to manage psychosocial needs.
Tobacco Use	Assessment of patients and families for smoking/tobacco use status. Referral for smoking cessation provided.
End of life care	Plan describing comprehensive end of life care incorporating patient preferences and evidence-based guidelines, and staff education.
Research Infrastructure for broad research agenda	
IRB	Yes. Central IRB where applicable.
Linkages with Research Organizations	Experience working with a university-based academic center or a NCI-designated Cancer Center cancer control study.
Clinical Research Nurses	Clinical Research Nurse, Clinical Research Association (CRA) or data management specialist that can support HSR, behavioral, outcomes studies appropriate for level III that leverage existing data systems at the site.
Electronic data linkages with NCI Research Effort	Yes. Leveraging site instance of Clinical Data Management System (CDMS)/Clinical Trials Management System (CTMS) to electronically submit data for Cooperative Group trials.
Capacity to participate in CER	Yes
Capacity to conduct cost effectiveness research	Yes
Dissemination and Implementation Research	Physician champion Commitment from executive management to implement and redesign cancer care based upon research.
Data capabilities	Data manager; project coordinator; level 2 plus have good data on multi-morbidity and access to resource use by patients (i.e., utilization and cost or payment data).
Network participation -ability to do cross-site data collection and research	Yes. Participate in network data harmonization on complex projects involving both resource use and clinical data.