

Mini Supporting Statement A For
“Questionnaire Cognitive Interviewing and Pretesting (NCI)”
0925-0589, Expiration Date 04/30/2014

Title of Sub-Study: Development of Consensus Measures of Distress for the Grid Enabled Measures – Distress Measurement (GEM-DM) Workspace

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Section A.

A1. Circumstances Making the Collection of Information Necessary

Section 410 of the Public Health Service Act (42 USC § 285) authorizes the collection of the information. The Behavioral Research Program (BRP), located in the National Cancer Institute’s (NCI’s) Division of Cancer Control and Population Sciences (DCCPS), initiates, supports, and evaluates both basic behavioral research efforts and research that supports cancer interventions. Its mission is to increase the breadth, depth, and quality of cancer prevention and control in behavioral research.

The development of quality measures for research is an important endeavor. In regards to measurement of distress, the National Cancer Comprehensive Network (NCCN) established guidelines for distress screening in 1997, and in the current revised guidelines, the importance of treating distress has been an essential component of psycho-social oncology (Holland, et al, 2013). Multiple calls for further research into the efficacy, outcomes, models and costs of distress screening implementation have been made (Carlson, et al, 2013, Thombs & Coyne, 2013). The proposed project is a step that NCI, because of its reach in the research community and connections with community based cancer programs, can execute to facilitate the next research steps in distress measurement.

To facilitate the development of consensus measures for distress measurement, the BRP developed the GEM Website (<https://www.gem-beta.org/>). The website was created to promote quality research measures and support the goals of BRP as outlined in their mission statement by: (1) Increasing the breadth of research measures available to health science researchers, by way of a collaborative online system that encourages users to download from and contribute to an ever growing online database of research measures; (2) providing users with multiple associated measures for key constructs in psychosocial distress (e.g., Anxiety, Depression, Stress); and (3) implementing a user driven interactive rating system of database measures, insuring the highest quality measures are highlighted

The information collected from these surveys will be used by the Grid Enabled Measures-Distress Measures (GEM-DM) team as formative research to facilitate eventual data harmonization. The data obtained by participants to the survey will be used to drive consensus on the best measures of distress to improve assessment of this construct. The ultimate goal is to enable the use of common measures of distress that will eventually improve negative outcomes like distress in cancer survivors (**Attachment A**).

A2. Purpose and Use of the Information Collection

Building on GEM's collaborative technology and virtual community, the GEM-DM Website Workspace has two broad goals: 1) Utilize an interactive online system to enable users to search for, share, download, and rate validated distress measures that are tied to theoretically-based constructs; and 2) facilitate the sharing of harmonized data, resulting from the use of shared measures, through features that allow both clinicians and researchers to search, preview, upload, download and collaborate on important research questions.

The GEM-DM site will aid in the initiation of more effective studies through the promotion of shared measures and harmonized data. These aims fit well with the Department of Health and Human Services (HHS) goals of the Open Government initiative (see for more information: <http://www.hhs.gov/open/>) to make data more freely available for use by others and to drive consensus on health indicators that can be shared and used by researchers, practitioners, and local communities. Information from this project will be disseminated to the following stakeholders:

- American Psychosocial Oncology Society training programs
- Commission on Cancer as the accrediting agency for new psychosocial distress screening guidelines
- NCI Divisions for stimulation of research in this area as well as other interested NIH institutes (National Institutes of Nursing Research (NINR) and Mental Health (NIMH)).

A3. Use of Information Technology and Burden Reduction

The invitation is sent by email (**Attachment B**) and the survey is administered through a secure electronic platform utilized by NCI (Survey Monkey). Participant responses are exported to an excel file and will be tabulated and analyzed by the research team.

A4. Efforts to Identify Duplication and Use of Similar Information

While there are measure libraries and repositories available through other sources, few, if any, have on-going user ratings and none have examined the assessments available under the construct of "distress" in the context of new accreditation guidelines.

A5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

A6. Consequences of Collecting the Information Less Frequently

This is a one-time collection.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Though feedback collected under this generic clearance provides useful information for our project team, it does not yield results that can be generalized to the overall population of users of distress screening instruments. Other limitations will also be discussed where these data are referenced. Our hope is that our results will help foster research collaborations in the community

cancer center setting, where accreditation standards are currently implementing distress screening, by both data harmonization and shared clinical and practice interests. These types of collaborations would then result in maximizing the relevance of research in the clinical setting.

A8. Comments in Response to Federal Register Notice and Efforts to Consult Outside Agency

The GEM-DM initiative represents a collaborative effort between the Science of Research and Technology (SRTB) and Basic, Biobehavioral and Psychological Science (BBPSB) Branches in the Behavioral Research Program (BRP). This collaboration leverages multiple areas of expertise and branch interests including: technology development and application (SRTB) and measurement of psychological constructs (BBPSB). Collecting data through the GEM-DM virtual community allows us to do formative research with a broad range of stakeholders who will be affected by the new guidelines for measuring distress and will now have a way to share their input.

A9. Explanation of Any Payment or Gift to Respondents

No payment or incentives will be given to respondents.

A10. Assurance of Confidentiality Provided to Respondents

Personally identifiable information (PII) will be collected in this project. Respondents will be asked to provide their name or a user name as part of survey completion along with their email address. Their name will be linked to their comments and ratings in the GEM platform.

Should the participant choose to discontinue participating at any time during the survey, their information is erased.

A Privacy Act Notification statement (PANS) has been written and included on the survey

A request for Office of Human Subjects Research exemption was approved on July 22, 2013 (OHSRP #12028) declaring this study Exempt from IRB review (**Attachment C**).

A11. Justification for Sensitive Questions

No sensitive questions are asked on the survey.

A12. Estimates of Hour Burden Including Annualized Hourly Costs

Since this is a generic sub-study, the burden hour and costs to respondents are reported as a total for this project and are not annualized.

The full generic requested 6,000 hours and to date 305 hours have been used.

Table A12-1. Estimates of Hour Burden

Type of Respondent	Number of Respondents	Number of Responses Per Respondent	Average Burden Per Response (in hours)	Total Burden Hours
Individuals: Researchers, Clinicians, Cancer Control Advocates	100	1	15/60	25

Table A12-2. Total Cost to Respondents

Type of Respondent	Number of Respondents	Total Burden Hours	Wage Rate	Total Respondent Cost
Individuals: Researchers, Clinicians, Cancer Control Advocates	100	25	\$35.35	\$833.75

Hourly wage rates for Healthcare Practitioners and Technical Occupations is \$35.35 (based on http://www.bls.gov/oes/current/oes_nat.htm).

A13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital costs, operating costs, or maintenance costs for the respondents, other than their time.

A14. Annualized Cost to the Federal Government

This survey is estimated to cost the Federal Government \$26,100 (Table A.14-1).

Table A14-1. Cost to the Federal Government

Task	Estimated Cost
Staffing – Federal FTE; 2 FTE’s for 4 months – 10 hours/week	\$16,000
Staffing –Contractor time	\$10,000
Survey Monkey Costs	\$100
Total	\$26,100

A15. Explanation for Program Changes or Adjustments

This is a new generic sub-study.

A16. Plans for Tabulation and Publication and Project Time Schedule

The projected timeline:

Task:	Projected Time (after OMB approval):
Launch/promote survey	1 month
Promote survey until 100 responses received	1 to 2 months
Tabulate Data, enter on GEM workspace	3 to 5 months
Incorporate data as part of project presentation	6 months

Analysis of results will include the following:

- Tabulation and entering instrument ratings and comments onto the GEM-DM workspace.
- Tabulation of distress screening tools used by setting (e.g., research, clinical)

Results will be presented and published (aggregated with existing data) as part of the GEM-DM initiative encouraging data harmonization and collaborative research in the domain of distress measurement and screening. The results from this formative research include ratings and comments of distress measures from experts in the field of behavioral research and any publications or presentations will be mainly methodological in nature, concerning the procedures used to assess measures of distress, along with quantitative and qualitative summaries of participant feedback regarding those measures.

The entire results of the GEM-DM initiative will be included as part of an invited presentation at the American Psychosocial Oncology Society (APOS) annual meeting in 2014. APOS members are comprised of researchers and clinicians in the fields of oncology, psychiatry, psychology, social works and spiritual care who are interested in the psychosocial needs of cancer patients and survivors. The process of this specific proposed project, which is a component of the GEM-DM initiative, will be mentioned in the context of a larger GEM-DM presentation and publication as a step in the methodology. Publication outlets considered are in the fields of clinical oncology and psychosocial care.

A17. Reason(s) Display of OMB Expiration Date Is Inappropriate

The OMB Clearance Number, Expiration Date, and Burden Disclosure Statements will be displayed on the applications.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the Certification for Paperwork Reduction Act Submissions.

Attachments

- A: GEM-DM Survey**
- B: Email Invitation**
- C: OHSR Exemption**
- D: Brief Description of Measures Document**

References

Carlson LE, Waller, A & Mitchell, AJ. Screening for distress and unmet needs in patients with cancer: Review and recommendations. *J Clin Oncol* 2013; 30:1169-1177.2

Holland, JC, Andersen, B, Breitbart, WS, Buchman, LO, Compas, B, Deshields, TL, et al. Distress management. *J Natl Compr Netw* 2013; 11:190-209.

Thombs, BC & Coyne, JC. Moving Forward by Moving Back: Re-assessing guidelines for cancer distress screening. *J Psychosom Res.* 2013 Jul;75(1):20-22.