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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Bright IDEAS-Young Adults: Problem-Solving Skills Training to Reduce Distress among Young Adults with Cancer
Principal Investigator: Katie Devine, PhD, MPH

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to test a problem-solving skills training program called Bright IDEAS. If you take part in the research, you will be asked to complete an online survey at study entry and again at 3 months, 6 months, 12 months, and 24 months after you start the study. After the first survey, you will be randomly assigned (like flipping a coin) to either the Bright IDEAS intervention group or Enhanced Usual Care. Bright IDEAS involves receiving a list of resources for young adults with cancer and six 45-minute sessions with a trained interventionist who teaches skills to approach problems or challenges you face. Enhanced Usual Care involves receiving a list of resources for young adults with cancer. Your time in the study will take 25 minutes per survey, which will occur five times over the course of two years. For those randomized to the Bright IDEAS intervention, your time will also involve six 45-minute sessions.

Possible harms or burdens of taking part in the study may be emotional discomfort or loss of confidentiality. Possible benefits of taking part may be increased awareness of resources, improved problem-solving skills, and learning useful strategies of handling stress.

Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Katie Devine, PhD, MPH is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Devine may be reached at (732) 235-7549, 195 Little Albany Street, New Brunswick, NJ 08903.

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study: This study is sponsored by the National Cancer Institute.

Why is this study being done?
This study is being done to test a problem-solving skills training program called Bright IDEAS. This training program has been shown to help caregivers of children with cancer improve problem-solving skills and reduce distress associated with managing cancer treatment. In this study, we will see if the

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program can help young adult (YA) cancer patients improve problem-solving skills, better manage distress and negative affect during cancer treatment, and improve quality of life.

Who may take part in this study and who may not?
You may be included in this study if you have been diagnosed with any form of cancer, are currently receiving cancer treatment, and are currently 18 to 39 years old. You may not participate if you do not speak/understand English.

Why have I been asked to take part in this study?
You have been asked to take part in the study because you are a young adult cancer patient.

How long will the study take and how many subjects will take part?
This study will last about 5 years. Up to 344 people will take part in the study. Each person will be in the study for about 2 years.

What will I be asked to do if I take part in this study?
First, you'll be asked to complete an online survey (about 25 minutes) that asks about the challenges of managing cancer treatment as a young adult, your problem-solving skills, emotions, and quality of life.

Next, all participants will be randomly assigned (like flipping a coin) to one of two groups: Bright IDEAS intervention or Enhanced Usual Care group.

a. If assigned to the Bright IDEAS intervention group, you will receive a list of resources from the NCCN adolescent and young adult patient guidelines and be asked to complete six 45-minute sessions with a trained interventionist where the Bright IDEAS problem-solving strategies are taught and applied to challenges you discuss. The sessions are usually done once per week in person during your usual medical visit, or by phone or video-conference using a HIPAA compliant platform. We will ask for your permission to audio record these sessions for supervision and education of the trainers.
b. If assigned to the Enhanced Usual Care group, you will receive a list of resources from the NCCN adolescent and young adult patient guidelines. You will also continue to receive the usual psychosocial care available to you.

Regardless of group assignment, all participants will be asked to complete the survey again at 3 months, 6 months, 12 months, and 24 months (about 25 minutes each time).

What are the risks of harm or discomforts I might experience if I take part in this study?
There are no physical risks or side effects associated with participation in this study. However, it is possible that you may experience emotional discomfort during the training (if assigned to complete Bright IDEAS) or when completing the survey. If you should experience any discomfort, please discuss with your trainer or our staff, and we may refer you to a social worker or counselor. For survey items, you can choose not to answer any question if you want.

All paper records that could identify you will be stored in locked file cabinets in a secure location, and all electronic records will be downloaded using encryption and stored in password-protected files. Your identity on these records will be indicated by a number rather than by your name, and the code linking your name to this number will be maintained separately with very limited access to research team members. All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. All study staff is trained to keep all information about you confidential.

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Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may be becoming aware of resources available to you, improving your problem-solving skills, and learning useful strategies of handling stress. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
There are no alternative interventions available. Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to me to take Part in this study?
There are no costs to you associated with participation in this study.

Will I be paid to take part in this study?
You will receive a $25 gift card per each survey completed for surveys 1 through 4, and a $50 gift card for completing survey 5 (for a total of up to $150).

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. If you agree, your trainer (if assigned) will audio-record your sessions. Your research data, including audio-recorded sessions, will be identified with a unique number assigned to you upon study entry. Your name and other health information will not be stored in the same place as the survey data.

The study team will store audio recordings on a secure cloud-based file storage application. These recordings will be reviewed for trainer supervision and education, and to see if the trainer covers all the material intended for each session. We will keep an electronic file that links your name and ID number in a password-protected file and this will only be accessible by authorized study personnel. This link will be destroyed six years after the end of the study.

DatStat software will be used to administer the online surveys. DatStat uses a number of physical, technical, and administrative safeguards to protect data, including industry standard encryption of communication between the web browser and data center. These data will be accessed by authorized members of the study team using secure web portal. If you choose to complete surveys on paper, these will be labeled with your study number rather than your name and stored in a locked filing cabinet in a secure location.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require, such as laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug

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Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen to my information or biospecimens collected for this research after the study is over?

After information that could identify you has been removed, de-identified information collected for this research may be used by or distributed to investigators for other research without obtaining additional informed consent from you.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Katie Devine, PhD, MPH, 195 Little Albany Street, New Brunswick, NJ 08903.

Who can I contact if I have questions?

If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Katie Devine, PhD, MPH, Department of Pediatrics, Section of Pediatric Population Science, Outcomes, and Disparities Research at (732) 235-7549.

If you have questions about your rights as a research subject, you can contact the Rutgers IRB Director at: New Brunswick/Piscataway HealthSci IRB 335 George St., Liberty Plaza Ste. 3100, New Brunswick, NJ 08901, (732)235-9806, or the Rutgers Human Subjects Protection Program at (973) 972-1149, email us at humansubjects@ored.rutgers.edu, or write us at 65 Bergen St., Suite 507, Newark, NJ 07107.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is The Purpose Of The Research And How Will My Information Be Used?

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You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What Information About Me Will Be Used?

- All information in your medical record
- Hospital discharge summaries
- Medical history or treatment
- Medications
- Consultations
- Emergency Medicine reports

Who May Use, Share or Receive My Information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators Involved In The Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Non-Rutgers Investigators On the Study Team at Memorial Sloan Kettering Cancer Center, New York City, NY, University of Rochester, Rochester, NY, and Moffitt Cancer Center, Tampa, FL
- The National Cancer Institute, the sponsor of this study

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I Be Able To Review My Research Record While The Research Is Ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have To Give My Permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision: Katie Devine, PhD, MPH, 195 Little Albany Street, New Brunswick, NJ 08903.

How Long Will My Permission Last?

There is no set date when your permission will end. Your health information may be studied for many years.

The following statements are about your understanding of this research study. Please choose "True" or "False" for each statement:

(True/False) 1. Participation in this study is completely voluntary and I can change my mind at any time.
(True/False) 2. If I agree to participate, I will be asked to complete surveys at five time points over the

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course of 2 years.

(True/False) 3. If I agree to participate, I get to choose which group I get assigned.

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Audiotaping
We are asking for your permission to audiotape your sessions with the trainer, if assigned to the Bright IDEAS-YA group as part of the research. You do not have to consent to be recorded in order to take part in the main research.

The recordings will be used for analysis by the research team, supervision of trainers, and education of new trainers.

The recordings will include your voice, which may identify you. The recordings will be labeled using a number rather than your name.

After your session, your trainer will transfer the recording from the recording device to the study staff through direct transfer on a computer or encrypted electronic transfer. The digital recordings will be stored on the PI's cloud-based secure drive and destroyed after results of the study are published. The recordings will not be used or distributed to investigators for other research. The investigator will not use the recordings for any other reason than those stated in the consent form without your written consent.

Do you give permission to audio-record as described during participation in this study?
Please initial one of the lines below to indicate whether you agree, or do not agree, to provide permission to audio record.

____Yes, I agree to provide permission to audio record.
____No, I do not agree to provide permission to audio record.

AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____