Study Type and Performance Site Information

Type of study:

[**x**] **Standard or Expedited**
[ ] Exempt
[ ] Grant Review
[ ] Comparative Effectiveness Research
[ ] Non-Human Subject Determination
[ ] Quality Improvement/Non-Research Determination
[ ] IRBshare or Other Agreement
[ ] Coordinating Center ONLY
[ ] I am not sure

Please indicate which Committee is most appropriate to review your project:

[**x**] **Social and Behavioral Sciences**
[ ] Health Sciences

Are there sites in this study in which the VU PI is responsible other than Vanderbilt University or Vanderbilt University Medical Center, including all VU clinics and hospitals?

[**x**] **Yes**
[ ] No

Are the sites "Engaged in the Research"?

[ ] yes
[**x**] **no**
[ ] both engaged sites and not engaged sties

Please list all Performance Sites "Not Engaged" in the research:

Various locations not yet identified. They will be the clinical offices of participating mental healh professionals (MHPs). Each MHP will fill out an Informed Consent Document as a participant in this study.

Are any of these sites international?

[**x**] **Yes**
[ ] No

Please list all international sites.

The PI, Nilgun Ongider-Gregory, Ph.D., is a research psychologist from Turkey. At some point in the future, Dr. Ongider-Gregory will use the same testing instruments to study families in Turkey.

Is this project cancer-related?

[ ] Yes
[**x**] **No**

Study Purpose and Description

Provide a brief abstract of the study in lay language. The IRB Committees are comprised of scientists with varied backgrounds, non-scientists, and community members.

Parental alienation is a mental condition in which a child - usually one whose parents are engaged in a high-conflict separation or divorce - allies himself or herself strongly with an alienating parent and rejects a relationship with the target parent without legitimate justification. In contrast, parental estrangement refers to a child's rejection of a parent for good reason, such as a history of abuse or neglect. In both clinical and forensic circumstances, it is important to distinguish alienation and estrangement. The purpose of this research is to identify questionnaires or psychological tests that will help an evaluator distinguish alienation and estrangement.

Expected duration of the study.

2 years

The IRB needs to understand how this study adds to the knowledge on this topic in order to be able to judge the risks and benefits to the research participants.

Divorce is an important problem having many psychological, social, and legal implications. Parental alienation (PA) is a serious condition that affects hundreds of thousands of children and families in the United States and comparable numbers in other countries. PA has been observed for many decades and has been described and discussed in the scientific literature of mental health professionals, in legal literature and precedents, and in popular literature. PA can be conceptualized as a cognitive-emotional condition of the child (e.g., the child has a false belief that the rejected or "target" parent is evil, dangerous, or not worthy of love) or an aberration in the relationship between the child and the rejected parent (e.g., absence of communication and camaraderie between child and parent, even though previously they enjoyed a loving, nurturing relationship). It is essential to recognize that in PA the child's rejection of the target parent is without legitimate justification. If a parent was abusive or severely neglectful, the child's rejection of that parent might be legitimate, and does not constitute PA. The target parent may not be a "perfect" mother or father and the target parent may have contributed in some way to the child's dislike of him or her. However, the essential feature of PA is that the child's rejection of the target parent is far out of proportion to anything that parent has done to justify the rejection (Lorandos, Bernet, & Sauber, 2013).

Parental acceptance-rejection theory (PARTheory) is a useful perspective for evaluating and studying PA. PARTheory is an evidence-based theory of socialization and lifespan development. It addresses the implications of parental acceptance and rejection for the individual's personality and psychological adjustment (Khaleque & Rohner, 2002). The psychological adjustment of children tends to be seriously affected by parental rejection. There is wide agreement about the importance of the quality of parent-child interaction, which mainly include satisfying children's needs for healthy psychological development. According to PARTheory, the warmth dimension of parenting has to do with the affective tenor of the parent/child relationship, and with the verbal, physical, and symbolic gestures parents use to relate to children. Caregivers can be located along a continuum of the warmth dimension, with one end signaling parental acceptance and the other end parental rejection (Rohner, 1986). PARTheory provides a sensitive, reliable perspective as well as objective measures for identifying and assessing children's perceptions of the attitudes and feelings of their mothers and fathers (Rohner & Khaleque, 2005).

We propose to compare 20 families in each of four groups within both the United States and Turkey. Thus, the total sample will include 80 families in each country. Most of these families will come to the attention of the research team because they are starting a psychiatric or psychological child custody evaluation. Some will come to the attention of the research team because they are starting a psychotherapy program with a mental health professional (MHP). During the custody evaluation or psychotherapy program, the parents and children will experience multiple interviews and will most likely take several psychological tests. We will contact several forensic psychiatrists and psychologists in Tennessee and in other states, who will help us identify families appropriate for this research. In addition, some families will be contacted through ResearchMatch.

The research groups include:

Alienated children. This group includes 20 families in which the parents are divorced or separated, and the children manifest contact refusal. Expert MHPs will determine as definitely as possible that the children refuse without good cause to have contact with parent.

Estranged children. This group includes 20 families in which the parents are divorced or separated and the children manifest contact refusal. Expert MHPs will determine as definitely as possible that the children were physically, sexually, or emotionally maltreated by one parent, so the children may have due cause to refuse contact with that parent.

Normal Controls. This group includes 20 families in which the parents are divorced or separated, but are not experiencing high conflict. The children have a satisfactory relationship with both parents. They could be families who have come to a clinic for evaluation or counseling for some other problem. Some of this group will be contacted through Research Match.

Intact Families. This group includes 20 families in which the children and parents live together in one household. This group will be contacted through Research Match.

The minimum age for the children in the U.S. and in Turkey will be 9 years old. In Turkey, it was found that the Child PARQ is useful for children 9 years old and older (Varan, 2003).

We propose to use the following measures:

• Child version of the Parental Acceptance-Rejection Questionnaire, Mother form (Child PARQ, Mother)
• Child version of the Parental Acceptance-Rejection Questionnaire, Father form (Child PARQ, Father)
• Child version of the Personality Assessment Questionnaire (Child PAQ)
• Personal Information Form - Youth Version (PIF Youth)

Thus, each child will complete these four questionnaires or tests on-line. The four documents will be folded into one long document, so it will seem like one questionnaire to the participants. Although the final questionnaire is called "Personal Information Form," it does not actually have personally identifying information. The PIF asks for the child's age, gender, ethnicity, language, religion, and education. These activities will be in addition to the procedures of the custody evaluation, but are the same type of questionnaires or psychological tests that are sometimes used in child custody evaluations.

We predict that the tests and questionnaires that we administer will distinguish the four groups of children, Alienated children, Estranged children, Normal Controls, and Intact Families. Specifically, we predict that the mean Child PARQ score for the preferred parent among alienated children will be very low (i.e., perceived acceptance) and the mean Child PARQ score for the alienated (target) parent will be very high (i.e., perceived rejection). Additionally we expect the overall mean Child PARQ score for the rejected parent among alienated children will be significantly higher (i.e., more perceived rejection) than among estranged children. And we expect the overall mean Child PARQ score for the rejected parent among estranged children will be significantly higher than among normal control children. We also expect the Child PAQ scores - revealing children's overall psychological adjustment - will be significantly higher (i.e., will show more psychological maladjustment) among alienated children than among estranged children. In turn we expect Child PAQ scores of estranged children will be significantly higher than among normal control children. Insofar as these predictions prove to be correct, this research will show that the Child PARQ and the Child PAQ are useful in the clinical and forensic evaluation of alienated and estranged children. Furthermore, these tests will help clinical and forensic evaluators distinguish alienated from estranged children.

The principal investigator for this research is Nilgün Öngider-Gregory, Ph.D. Dr. Öngider-Gregory is a citizen of Turkey, who will be in the U.S. for one year during 2014-15 for the purpose of conducting this research. The sub-Investigator for this research will be Bradley W. Freeman, M.D., an assistant professor in the Department of Psychiatry, Vanderbilt University School of Medicine. Dr. Freeman works in the Vanderbilt Psychiatry Outpatient Clinic, where we hope to recruit subjects for this research. Ronald P. Rohner, Ph.D., has assisted in the design of the research and will assist in the analysis of data. Dr. Rohner is an authority on PARTheory and the author of the PARQ, the questionnaire that will be

administered in this research. William Bernet, M.D., will assist in identifying and recruiting appropriate families to participate as subjects of this research in the U.S. Dr. Bernet is an authority regarding PA and the method for conducting child custody evaluations.

References

Khaleque, A., & Rohner, R. P. (2002). Perceived parental acceptance-rejection and psychological adjustment: A meta-analysis of cross-cultural and intracultural studies. Journal of Marriage and Family, 64, 54-64.
Lorandos, D., Bernet, W., & Sauber, S. R. (eds.) (2013). Parental alienation: The handbook for mental health and legal professionals. Springfield, IL: Charles C Thomas.
Rohner, R. P. (1986). The warmth dimension: Foundations of parental acceptance-rejection theory. Beverly Hills, CA: Sage Publications, Inc. Reprinted by Rohner Research Publications.
Rohner, R. P., & Khaleque, A. (Eds.) (2005). Handbook for the study of parental acceptance and rejection (4th ed.). Storrs, CT: Rohner Research Publications.
Varan, A. (2003). Reliability and validity of the Turkish child PARQ/Control (mother and father forms) and the Turkish child PAQ. Retrieved March 24, 2014, from http://www.azmivaran.com.

Research, Activities, Procedures, and Schedule of Events for Study Participants

Please check all that apply to your study and describe each below.

[ ] Behavioral Observation
[ ] Randomization
[**x**] **Blinding**
[**x**] **Surveys, Interviews, Questionnaires**
[ ] Document and Artifact Collection
[ ] Deception, Withholding or Postponing Medications/Treatments, or Imposing other Restrictions
[ ] Audio/Video Recording
[ ] Sham Procedure
[ ] Specimen Collection and/or Storage

DATA COLLECTION, STORAGE OF DATA/SPECIMENS, AND/OR ISSUES OF CONFIDENTIALITY - Describe the procedures that will be utilized to protect the privacy of the research participant. Include who will have access to the research information (for example, video/audio recordings, discovering information about the participant that could be harmful if released such as mental illness, genetic information, sexual preference, drug abuse, etc.) and where it will be stored.

The children will complete the questionnaires on-line, through the REDCap system. After being submitted, the data will be available to Dr. Öngider-Gregory and Dr. Bernet at their office in the Oxford House, Vanderbilt University School of Medicine. The questionnaires will be held in a locked file cabinet. At some later point, the person conducting the child custody evaluation will send a single sheet of paper indicating his or her conclusions regarding each child. All the documents will be identified by a number, so no personal identifying information will be on either the questionnaires or the conclusions of the custody evaluation. However, the names of family members will be on the Consent to be Contacted Regarding Research and the e-mail correspondence with the parent regarding informed consent.

No personal, identifying information will be on any of the questionnaires that are used in this research. The person conducting the child custody evaluation or psychotherapy will know who the subjects are because he or she obtained the Consent to be Contacted Regarding Research. No personal, identifying information will be put on the questionnaires that go to the research team. However, the names of the subjects will be on the consent forms.

Describe how the confidentiality of participants' data will be assured. Include a description of any issues specific to the study that might increase the risk of breach of confidentiality. Describe how codes will be generated if codes are used to protect identities, and who will have access to such codes. If a certificate of confidentiality will be provided, include the name of the person holding the certificate. Describe the final disposition of research data when the study is concluded (e.g., will information be destroyed, will the PI maintain the information indefinitely, etc.).

We will obtain a list of 8-digit random numbers from random.org, a free website. We will use those unique numbers to identify each child's responses to the questionnaires. The same unique numbers will identify the form on which the MHP reports whether each child belongs to the group of Alienated children, Estranged children, or Normal Controls.

BLINDING - Describe who will be blinded and if/when research results or previously blinded treatment assignments will be made available to participants. Include the provisions for breaking the blind (e.g., emergency situations, participant's request, etc.).

The MHP who is conducting the child custody evaluation or psychotherapy will not know the results of the questionnaires that are completed by the subjects. We do not anticipate that there will be any need or opportunity to break the blind.

It is not possible to guarantee that the person who is conducting the child custody evaluation or psychotherapy will be totally blind to the data in the questionnaires. For example, it is possible and not preventable that the child, after completing the questionnaires, will simply tell the custody evaluator or therapist during a subsequent interview about some features of the questionnaires.

SURVEYS, INTERVIEWS, AND QUESTIONNAIRES - If surveys, interviews or questionnaires will be used as part of this study, indicate who will conduct the survey, interview or questionnaire and his/her qualifications. In addition, describe the setting and mode of administering the instrument (e.g., by telephone, one-on-one, group, etc.) and attach a copy of the instrument.

Questionnnaires will be administered on-line through the REDCap system. The child will be sitting in a room alone at the home of one of his parents..

Please indicate all procedures and activities performed for research purposes only and the frequency at which they occur in the study (e.g., skin biopsy, 3 times).

Procedure/Activity	Frequency
Questionnaire	Once

If all of your study is minimal risk, please indicate the categories that it fits 45 CFR 46.110 or 21 CFR 56.110:

[ ] N/A: Study is greater than minimal risk or Standard
[ ] (F)(1) Drugs or devices where no IND/IDE is required
[ ] (F)(2) Collection of blood by stick or venipuncture
[ ] (F)(3) Prospective collection of specimens by non invasive means
[ ] (F)(4) Collection of noninvasive data through routine clinical practice
[ ] (F)(5) Research on materials that have been collected for non research
[ ] (F)(6) Collection of data from voice, video, digital or image recordings
[**x**] **(F)(7) Research on individual or group characteristics (surveys)**

Please describe type of survey or focus group, evaluation methods used.

We propose to use the following measures:

- Child version of the Parental Acceptance-Rejection Questionnaire, Mother form (Child PARQ, Mother)
- Child version of the Parental Acceptance-Rejection Questionnaire, Father form (Child PARQ, Father)
- Child version of the Personality Assessment Questionnaire (Child PAQ)
- Personal Information Form - Youth Version (PIF Youth)

Thus, each child will complete these four questionnaires or tests on-line. The four documents will be folded into one long document, so it will seem like one questionnaire to the participants. Although the final questionnaire is called "Personal Information Form," it does not actually have personally identifying information. The PIF asks for the child's age, gender, ethnicity, language, religion, and education. These activities will be in addition to the procedures of the custody evaluation, but are the same type of questionnaires or psychological tests that are sometimes used in child custody evaluations.

Data and Safety

Describe how the risks to participants are minimized (e.g., screening to assure appropriate selection of participants, identify standard of care procedures, sound research design, safety monitoring and reporting).

The families who participate in this research have already arranged to have a child custody evaluation conducted by an experienced forensic psychiatrist or psychologist or outpatient psychotherapy by a MHP. (Also, some families will be contacted through ResearchMatch. A child custody evaluation consists of several components, including: multiple interviews; psycholgical testing; collecting data from collateral informants, such as stepparents, grandparents, teachers, therapists, and pediatricians; and reviewing legal, educational, and clinical records. The questionnaires used in this research (the Personality Assessment Questionnaire and the Parental Acceptance-Rejection Questionnaire) are generally similar to psychological tests and questionnaires that are routinely used in child custody evaluations.

It should take each child subject about 30 to 40 minutes to complete on-line the questionnaires used in this research, which is a small amount of time compared to their participation in the child custody evaluation. The participants will be at a comfortable location, i.e., at home with one of their parents. Also, they will be told they can discontinue the process at any time if they wish to do so.

Describe how the risks to participants are reasonable in relation to anticipated benefits (e.g., includes benefits to the individual as well as to human kind, indicate how the risks are justified in this population).

Child custody evaluations are an important event for many families who are experiencing divorce. It is very important for custody evaluators to understand the child's perception of his or her parents and to identify and correctly diagnose parental alienation (when the child refuses contact with a parent without a good cause) and parental estrangement (when a child refuses contact with a parent for a good reason, such as a history of abuse or neglect). In many evaluations, it is hard to distinguish alienation from estrangement. We believe that if this research is successful, the questionnaires that we are studying (especially the Parental Acceptance-Rejection Questionnaire) will assist future custody evaluators in distinguishing alienation and estrangement.

The data obtained from each family will not be made available to the person conducting the custody evaluation or psychotherapy of that family because we want the MHP's analysis and conclusions to be fully independent of the results of the research questionnaires. Therefore, this research will not directly benefit the family members who participate as subjects. However, this type of research should greatly benefit family members in the future who are experiencing a difficult divorce.

Is there a data safety monitor or board/committee to review this study for safety and adherence to the study protocol?

[ ] Yes
[**x**] **No**

Provide a general description of the data and safety monitoring plan.

The children will complete the questionnaires on-line, through the REDCap system. After being submitted, the data will be available to Dr. Öngider-Gregory and Dr. Bernet at their office in the Oxford House, Vanderbilt University School of Medicine. The questionnaires will be held in a locked file cabinet. At some later point, the person conducting the child custody evaluation will send a single sheet of paper indicating his or her conclusions regarding each child. All the documents will be identified by a number, so no personal identifying information will be on either the questionnaires or the conclusions of the custody evaluation. However, the names of family members will be on the Consent to be Contacted Regarding Research and the e-mail correspondence with the parent regarding informed consent.

Describe plans for monitoring the progress of trials and the safety of participants (e.g., timing of DSM reviews and reports, planned interim analysis, etc.).

The children who participate in this research will spend about 30 to 40 minutes on-line filling out the questionnaires. It is unlikely they will experience anything more than minimal physical or psychological discomfort in filling out the questionnaires. During that task, they will be at home with one of their parents. If a subject were to have transitory distress related to the questionnaires, that will be addressed by the child's parent who has given consent for the child's participation and is generally familiar with the research project.

Describe plans for assuring compliance with requirements regarding the reporting of adverse events (AEs), including plans for reporting of AEs to the IRB and appropriate regulatory agencies.

If an adverse event were to occur, the child's parent will report that fact to Dr. Öngider-Gregory and Dr. Bernet, who will report it to the IRB.

Describe plans for assuring that any action resulting in a temporary or permanent suspension of a federally funded research project is reported to the grant program director responsible for the grant.

The proposed research is not federally funded.

Describe plans for assuring data accuracy and protocol compliance.

The participating MHPs who are helping to recruit families will be advised how to engage parents in that discussion. With regard to the child's completing the questionnaires on-line, the parents will be advised to let the child do that task in a room alone. Likewise, when the children start to respond to the questionnaires, they will be told that they should be in a room alone. The on-line computer program will prompt the child to complete all the questions.

Is Vanderbilt going to be the Coordinating Center?

[**x**] **Yes**
[ ] No

Protocol and/or case report form development and/or distribution?

[**x**] **Yes**
[ ] No

Sample consent form development and/or distribution?

[**x**] **Yes**
[ ] No

Describe the coordinating center's role in reviewing modifications by the collaborating institution of sample consent information related to risks or alternative procedures to assure changes are appropriately justified.

We do not anticipate that there will be any reason for the collaborating mental health professinals to modify the consent form.

Critical documents (study) management?

[ ] Yes
[**x**] **No**

Site selection and training in study procedures?

[**x**] **Yes**
[ ] No

Describe site selection, qualifications, site training and how training will be provided.

Dr. Bernet will contact colleagues at Vanderbilt and at other locations in the U.S., who are known to be experienced in conducting child custody evaluations and other MHPs who are experienced in treating families of divorce. Dr. Bernet will provide these colleagues with the research proposal and the form, Consent to be Contacted Regarding Research. Also, Dr. Bernet will provide the custody evaluators and other MHPs a document, Information for Participating Mental Health Professionals, which explains in detail, step-by-step, how to recruit participants to this research.

Assuring informed consent is obtained from each participant enrolled at the participating centers?

[**x**] **Yes**
[ ] No
[ ] N/A

Describe the mechanisms to be employed.

The participating MHPs will identify parents who agree to be contacted regarding this research. (See document, Consent to be Contacted Regarding Research.) Then, Dr. Bernet or Dr. Öngider-Gregory will contact by e-mail those parents of prospective subjects, explain the research project to them, and obtain informed consent. (See document, Procedure for Informed Consent by E-mail.) If the parent gives consent, the parent will help the child sign onto the REDCap website and log in. After logging on, the child will receive basic information regarding the research and will provide assent on-line. (See document, Assent Document for Research Study.)

Tracking of serious adverse events and unanticipated problems involving risk to participants or others, reporting to participating centers and regulatory reporting?

[**x**] **Yes**
[ ] No

Describe who will be responsible for receiving and reviewing serious adverse events and unanticipated problems involving risk to participants or others reported by the participating centers and how those reports will be disseminated to other participating centers, the coordinating center and participating site IRBs, sponsors, data safety monitoring boards and applicable regulatory agencies.

If an adverse event were to occur, the child's parent or the involved MHP will report that fact to Dr. Öngider-Gregory and Dr. Bernet, who will report it to the IRB and to other individuals who need to know about the event.

Will the coordinating center receive/store private, identifiable information about study participants from the participating centers?

[ ] Yes
[**x**] **No**

Will coordinating activities include responsibilities that require contact with participants from the participating centers?

[ ] Yes
[**x**] **No**

Statistical Analysis?

[**x**] **Yes**
[ ] No

Please describe who will perform the statistical analysis and the qualifications of the individual performing the statistical analysis. In addition, describe whether the analysis will involve identifiable samples/information.

Statistical analysis will be performed by the PI, Dr. Öngider-Gregory, with the consultation of Dr. Rohner. The analysis will not involve identifiable information.

Publication or Presentation of Study Results?

[**x**] **Yes**
[ ] No

Do you have any other Coordinating Center responsibilities?

[ ] Yes
[**x**] **No**

Is Vanderbilt also recruitment site?

[**x**] **Yes**
[ ] No

Please select the phase of study.

[ ] Phase I
[ ] Phase I/II combined
[ ] Phase II
[ ] Phase III,
[ ] Phase IV
[**x**] **N/A**

Does this study require registration with clinicaltrials.gov?

[ ] Yes
[**x**] **No**

Subject Population(s)

Is this a study in which you will have interaction with individuals?

[**x**] **Yes**
[ ] No

Accrual Goal: What is your total accrual goal?

180

Total number of participants stated in the protocol to be studied at all sites (regardless of PI).

360

Does this study target one gender or specific social/ethnic group(s)?

[ ] Yes
[**x**] **No**

Is the population being enrolled in this study at high risk for incarceration?

[ ] Yes
[**x**] **No**

Check all that apply (*Complete the appropriate supplemental information as applicable):

[ ] N/A
[**x**] **Children/minors***
[ ] Cognitively impaired - comatose/traumatized*
[ ] Pregnant women/fetal tissue/placenta*
[ ] Prisoners*

Place a check in the box beside the category that best describes your proposed research. If the research study includes two pediatric populations (i.e. a healthy control/donor group and a patient/recipient group), identify the appropriate category and provide justification for each group individually.

[**x**] **(45 CFR 46.404; 21 CFR 50.51) This proposed research poses no greater than minimal risk to children.**
[ ] (45 CFR 46.405; 21 CFR 50.52) This proposed research poses greater than minimal risk to children and includes an intervention or procedure that DOES hold out the prospect of a direct benefit for the individual child or a monitoring procedure that is likely to contribute to the child's well-being.
[ ] (45 CFR 46.406; 21 CFR 50.53) This proposed research poses greater than minimal risk to children and is presented by an intervention or procedure that DOES NOT hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, BUT is likely to yield generalizable knowledge about the subject's disorder or condition.
[ ] (45 CFR 46.407; 21 CFR 50.54) This proposed research does not meet the requirements of Category 1, 2, or 3 listed above. The IRB will submit the study to the Office of Human Research Protections (OHRP) for review and certification.

Please explain why the proposed research falls under this category.

This research involves children whose parents are divorced and there is disagreement over the parenting time arrangements for the children. It has been arranged for the parents and children to participate in a child custody evaluation, which typically takes place over several days. Alternatively, it has been arranged for the parents and children to participate in some form of psychotherapy. The children who agree to participate in this research study will be asked to complete on-line four questionnaires. It should take about 40 minutes to complete that task, and the children can takes breaks as needed during that time. These questionnaires are the type of activity that routinely occurs during the course of child custody evaluations and in most psychological evaluations.

Please explain how adequate provisions are made for soliciting the assent of the children.

After consent is obtained from one of the parents, the parent will explain the general plan of the research to the child(ren). The parent will arrange for each child individually to sit at a computer at the parent's home. The parent will help the child log on to the REDCap website and to this research project. The child will be welcomed to the website. (See document "Assent Document for Research Project.") The parent will be in the room while the child reads the explanation of the research and will answer general questions that the child may have. If the child agrees to continue with the questionnaire, the parent will leave the room. (The four questionnaires are collapsed into one long questionnaire on the website.) Since the child is participating on-line, the child will not sign the assent form.

Please explain how adequate provisions are made for obtaining permission/consent of their parents or guardians.

Several mental health professionals (MHPs) at various locations in the U.S. (and in Turkey) will help us recruit families for this research. The MHP will explain the research project to parents in a general way and will give them a short statement to read, Information Regarding Psychosocial Research: "A Bicultural Comparison." If the parent expresses an interest in allowing their child to participate, the MHP will ask them if they will consent for one of the research team to conact them to provide more detailed information. If the parent gives consent, the MHP will notify the research team. When that occurs, a member of the research team will contact the parent by e-mail and will follow the script in the document Procedure for Informed Consent by E-mail. The parent will acknowledge his or her consent by sending an e-mail reply to the research team.

Please explain any dissenting behaviors, that when observed, may result in the child being withdrawn from the research.

The child may verbally decline or refuse to participate in responding to the questionnaires. The child may become emotionally upset at reading the questionnaires, but we think that is very unlikely. (The research personnel, having done hundreds of child custody evaluations, have found that children almost always cooperate in the various activities that are involved in those evaluations.) However, if the child does become upset about some aspect of the research procedure, the parent who is nearby can remove the child from the computer and close the website. Of course, the parent and child will have been told that their participation is voluntary.

Recruitment

Describe the specific steps to be used to identify and/or contact prospective participants. (If applicable, also describe how you have access to lists of potential participants.)

Dr. Bernet will contact colleagues at Vanderbilt and at other locations in the U.S., who are known to be experienced in conducting child custody evaluations and in treating families of divorce. These MHPs, at Vanderbilt and elsewhere, will identify families who will be undergoing child custody evaluations or psychotherapy.

The MHP who is conducting the child custody evaluation or psychotherapy will say to the parents: "I want to tell you about a research project that pertains to your family. A research team at Vanderbilt University is studying how children and parents relate to each other. They are comparing families in the United States with families in Turkey. If your family participates in this project, it means that your children will fill out a questionnaire on-line. Please read this short description of the research project."

After the parents have read Information Regarding Psychosocial Research: "A Bicultural Comparison," the MHP will answer general questions about the research project. If the parents seem interested in allowing their children to participate, the MHP will say: "Will you agree to having someone from the research team contact you to tell you more information about this research project?" If the parent agrees, the MHP will ask them to sign the Consent to be Contacted Regarding Research.

In addition to the procedure described above, some families will be contacted through ResearchMatch. See the documents, ReseachMatch, First Contact (which will be sent to prospective parents directly from ResearchMatch) and ResearchMatch, Second Contact (which will be sent to prospective parents who express an interest in this project, by research team personnel).

Identify the criteria for inclusion and exclusion and explain the procedures that will be used to determine eligibility. If psychiatric/psychological assessments will be conducted (e.g., depression or suicidal ideation screenings), state who will administer, his/her experience, and how risks will be managed.

The inclusion criterion is simply that the family will be undergoing a child custody evaluation or psychotherapy for divorced families. There are no specific exclusion criteria. In addition, some families (such as intact families who are not divorced) will be contacted through Research Match.

Describe how the selection of participants is equitable in relation to the research purpose and setting.

Anticipated participants in this research are families undergoing a child custody evaluation. The people who will ultimately benefit from this research are families in the future who are undergoing a child custody evaluation. No ethnic group is either targeted or excluded.

Please indicate whether you plan to enroll any of the populations indicated below:

[ ] VU Medical Students/trainees
[ ] Students
[ ] Elderly/Aged - targeted
[ ] Subordinates/Employees
[ ] Females of childbearing potential
[ ] Terminally ill participants
[**x**] **Healthy Volunteers**
[ ] Other

Please identify ALL applicable recruitment methods:

[ ] N/A
[**x**] **Flyers**
[ ] Internet
[ ] Letter
[ ] Departmental Research Boards,
[ ] Mass E-mail Solicitation
[ ] Newspaper
[ ] Posters
[**x**] **ResearchMatch (IRB 090207)**
[ ] Radio
[ ] Telephone
[ ] Television
[ ] Social Media
[**x**] **Other**

Please describe other:

Dr. Bernet will contact colleagues at Vanderbilt and at other locations in the U.S., who are known to be experienced in conducting child custody evaluations and in treating families of divorce. These MHPs, at Vanderbilt and elsewhere, will identify families who will be undergoing child custody evaluations or psychotherapy.

The MHP who is conducting the child custody evaluation or psychotherapy will say to the parents: "I want to tell you about a research project that pertains to your family. A research team at Vanderbilt University is studying how children and parents relate to each other. They are comparing families in the United States with families in Turkey. If your family participates in this project, it means that your children will fill out a questionnaire on-line. Please read this short description of the research project."

After the parents have read Information Regarding Psychosocial Research: "A Bicultural Comparison," the MHP will answer general questions about the research project. If the parents seem interested in allowing their children to participate, the MHP will say: "Will you agree to having someone from the research team contact you to tell you more information about this research project?" If the parent agrees, the MHP will ask them to sign the Consent to be Contacted Regarding Research.

Will the study provide compensation to research participants?

[ ] Yes
[**x**] **No**

Do you agree to release study information to Vanderbilt-approved list services, web sites or publications? NOTE: Vanderbilt has a variety of list services and publications, such as the Clinical Trials Website. Posting research protocol information on research-related websites and other listing services, allows potential participants to search and find studies related to their condition or interest.

[ ] Yes, this information may be released as described in the lay summary.
[**x**] **No, do not release information to research-related web sites and other listing services.**

Does this study include a certificate of confidentiality or sensitive research information that must be hidden in the medical record?

[ ] Yes
[**x**] **No**

Radiation Procedures and Radioactive Drugs

Does this study involve any radiation ionizing procedures for research?

[ ] Yes
[**x**] **No**

Drugs, Devices, Biologics

Please check all that apply:

[**x**] **N/A**
[ ] Drug(s)/Biologic(s) or Placebo (inactive substance) Used for Research that HAVE an IND
[ ] Drug(s)/Biologic(s) or Placebo (inactive substance) used for Research that DO NOT have an IND [only include drugs that are being used outside of package insert labeling for indication, route of administration, dose, dosing frequency, dosage form, and/or population in which the drug is being used (i.e. children)]
[ ] Gene Transfer, Live, Recombinant, and/or Attenuated Microorganisms for Vaccination or Select Agents (Note: If any answer in this section is checked yes, approval from the Institutional Biosafety Committee is required.)
[ ] Device(s) Used for Research (devices may also include computer software, in vitro diagnostics, etc.)

PHI/Consent

Please indicate what you plan to do with regard to consent (check all that apply):

[ ] Consent
[**x**] **Waiver of Consent**
[ ] Consent was obtained in another study
[ ] Consenting not required

Which type of waiver is being selected (check all that apply):

[**x**] **Waiver of Documentation**
[ ] Alteration of Informed Consent Process
[ ] Waiver of Informed Consent Process/Waiver of Authorization

The IRB may waive the requirement to obtain a signed informed consent document for some or all of the participants. This is a waiver of signatures only. With this option, all of the other basic elements of informed consent are still present and are provided to participants.

[ ] The only record linking the participant to the research is the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Under this condition, each participant must be asked whether he/she wants to sign a consent document. The IRB must review and approve the consent document.
[**x**] **The research is minimal risk and involves no procedures for which written consent is normally required outside of the research context (e.g. phone surveys, collection of de-identified data from medical record or other chart review). The IRB must review and approve the consent document or script.**

Are you requesting a waiver of authorization to access (use) Protected Health Information (PHI)?

[ ] Yes
[**x**] **No**

Please describe the plan to protect the identifiers from improper use and disclosure.

We are not collecting PHI. The identifiers (i.e., name of child and name of parent) are on the consent form, such as the consent to be contacted. Those forms will be held in a locked file cabinet in a locked office.

Please describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

We are not collecting PHI. The consent forms that contain identifiers will be held in a secure location for 3 years following the completion of the research. Then they will be destroyed.

Please verify that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research.

We are not collecting PHI.

Will Protected Health Information (PHI) be accessed (used) in the course of screening/recruiting for this research?

[ ] Yes
[**x**] **No**

Does this research use or disclose Protected Health Information (PHI)?

[ ] Yes
[**x**] **No**

Conflict of Interest Disclosure

Is there a potential conflict of interest for the Principal Investigator or key personnel? • The PI is responsible for assuring that no arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research and no arrangement has been entered into where the amount of compensation will be affected by the outcome of the research. • Assessment should include anyone listed as Principal Investigator, or other research personnel on page 1 of this application. Please note that ownership described below apply to the aggregate ownership of an individual investigator, his/her spouse, domestic partner and dependent children). Do not consider the combined ownership of all investigators.

[ ] Yes
[**x**] **No**