Form RA-108
(Rev. 5/09)

THE UNIVERSITY OF MONTANA-MISSOULA
Institutional Review Board (IRB)
for the Use of Human Subjects in Research
CHECKLIST / APPLICATION

IRB Protocol No.: 187-09

At The University of Montana (UM), the Institutional Review Board (IRB) is the institutional review body responsible for oversight of all research activities involving human subjects outlined in the U.S. Department of Health and Human Services Office of Human Research Protection (www.hhs.gov/ohrp) and the National Institutes of Health, Inclusion of Children Policy Implementation (http://grants.nih.gov/grants/funding/children/children.htm).

Instructions: A separate registration form must be submitted for each project. IRB proposals are approved for three years and must be continued annually. **Faculty members** may email the completed form as a Word document to *IRB@umontana.edu*. **Students** must submit a hardcopy of the completed form to the Office of the Vice President for Research & Development, University Hall 116.

1. Administrative Information

Project Title: Motivational Interviewing Training: A pilot study	
Principal Investigator: Christine Fiore, PhD	Title: professor
Email address: christine.fiore@umontana.edu	
Work Phone:x2081	Cell Phone: 214-1698
Department: Psychology	Office location Skaggs 362

2. Human Subjects Protection Training

(All researchers, including faculty supervisors for student projects, must have completed a self-study course on protection of human research subjects ***within the last three years*** *(http://www.umt.edu/research/complianceinfo/IRB/) and be able to supply the "Certificate(s) of Completion" upon request. Add rows to table if needed.*

NAME and DEPT.	PI	CO-PI	Faculty Supervisor	Research Assistant	DATE COMPLETED Human Subjects Protection Course
Christine Fiore, PhD	X	☐	☐	☐	2009
Marc Steinberg, MD.	☐	X	☐	☐	pending
Steve Zellmer, LCPC,LAC	☐	X	☐	☐	pending
Zed Kramer, M.A.T.	☐	☐	☐	X	2009

3. Project Funding

Is grant application currently under review at grant funding agency? ☐Yes *(If yes, cite sponsor on ICF if applicable)* X No			Has grant proposal received approval and funding? ☐Yes *(If yes, cite sponsor on ICF if applicable)* ☐No	
Agency	Grant No.	Start Date	End Date	PI
Is this part of your thesis or dissertation? ☐Yes x No		If **yes**, date you successfully presented your proposal to your committee:		

For UM-IRB Use Only

IRB Determination:

_____ Approved Exempt from Review, Exemption # ____ *(see memo)*
_X_ Approved by Expedited/Administrative Review *(see* ***Note to PI****)*
_____ Full IRB Determination
_____ Approved *(see* ***Note to PI****)*
_____ Conditional Approval *(see memo)* - IRB Chair Signature/Date: _____
_____ Conditions Met *(see* ***Note to PI****)*
_____ Resubmit Proposal *(see memo)*
_____ Disapproved *(see memo)*

*** Note to PI:** Study is approved for one year. Use any attached IRB-approved forms (signed/dated) as "masters" when preparing copies. If continuing beyond the expiration date, a continuation report must be submitted. Notify the IRB if any significant changes or unanticipated events occur. Notify the IRB in writing when the study is terminated

Final Approval by IRB Chair: Sheila Hoffland Date: 10/27/09 Expires: 10/26/2010

SUBJECT INFORMATION AND INFORMED CONSENT

Title: Motivational Interviewing Training: A pilot study

Project Director: Christine Fiore, PhD, The University of Montana, Department of Psychology, Missoula, MT 406-243-2081.

Special instructions: This consent form may contain words that are new to you. If you read any words that are not clear to you, please ask the person who gave you this form to explain them to you.

Purpose: The purpose of this research study is to learn how to improve training and dissemination of empirically supported treatments. Motivational Interviewing has been shown to be an effective intervention to evoke behavior change in those seeking assistance across a wide range of behavioral areas. Training of community practitioners is essential to ensure best practices are offered to those seeking care. This study will study the naturalistic process of training and dissemination of Motivational Interviewing.

Procedures: If you agree to take part in this research study, you will be given written measures to complete prior to the start of the training (time 1) at the end of the training (time 2), 1 month post-training (time 3), 3 months post-training (time 4), and 6 months post-training (time 5). These measures will ask about your professional background, knowledge, expectations, feelings, and commitment to the training. All participants in the training will be given the opportunity for audiotape feedback as a component of follow-up. You can also choose to submit an audiotape of an interaction with a client at follow-up times 3-5 that will be coded and you will be provided feedback on your skills as a component of follow-up. Your ratings will be kept as part of the study if you choose to participate in this component of the study. You will need to attain signed consent from your clients who agree to audiotaping and keep that for your records. For children, you will obtain parental consent, and for children 10-18, a better age for use of these skills, you will get their assent to be taped as well. Your client will not be coded or evaluated as a part of this study.

Time 1 and time 2 assessments will take place at the 2- day training at the Doubletree Hotel. Times 3-5 will take place at the follow-up designation of your choosing, typically your place of professional practice. You will agree to submit your materials by email encrypted using Axantum Acrypt (we will provide you the method) at times 3 (1 month post), 4 (3 months post) and 5 (6 months post). It will take 10-15 minutes to complete the written material, and audiotapes will require a minimum of 15 minutes of taped interaction with a client for coding.

Risks/Discomforts: Participation in this training, the written materials, and audiotaping may create mild discomfort related to role plays in the company of others, feeling evaluated for your skills, and receiving feedback about skill development. You may discontinue at any time or choose not to participate in any aspect of this study. However, the goal is to make the learning experience as positive and worthwhile as possible to allow you to gain as much competence in performing this empirically supported treatment effectively with the people you serve as a professional. We appreciate feedback to make this learning experience optimally meet your needs.

Benefits: Although may not personally benefit from taking part in this study above beyond that offered to all training participants, the hope is to contribute to the scientific knowledge base about effectively disseminating empirically supported treatments to professionals in the community. Through your willingness to complete the study we will learn more about training methodology and practices that encourage and support community practitioners in acquiring the new skills and innovations.

Confidentiality: Your written materials, and audiotapes (if you choose to submit them) will be kept private and all of your materials will be assigned a number code for data analysis. Your consent form will be kept separate from your final number-identified materials which will all be kept in locked file cabinets. Only the trainers will know your identity on coded audiotapes in order to provide personal feedback to you as a component of the

training. Coding of audiotapes and data entry will only be conducted with the number identification. If the results of this study are written in a scientific journal or presented at a scientific meeting, your name will never be used. I will sign the separate permission to use audiotape below to allow for use of a transcript for future training or publication and any identifying information about you or your client would be not be used.

Compensation for Injury: Although we do not foresee any risk in taking part in this study, the following liability statement is required in all University of Montana consent forms.

> In the event that you are injured as a result of this research you should individually seek appropriate medical treatment. If the injury is caused by the negligence of the University or any of its employees, you may be entitled to reimbursement or compensation pursuant to the Comprehensive State Insurance Plan established by the Department of Administration under the authority of M.C.A., Title 2, Chapter 9. In the event of a claim for such injury, further information may be obtained from the University's Claims representative or University Legal Counsel. (Reviewed by University Legal Counsel, July 6, 1993)

Voluntary Participation/Withdrawal: Your decision to take part in this research study is entirely voluntary. You may refuse to take part in or you may withdraw from the study at any time without penalty or loss of benefits in training to which you are normally entitled.

Questions: If you have any questions about the research now or during the study contact: Christine Fiore, PhD 406-243-2081. If you have any questions regarding your rights as a research subject, you may contact the Chair of the IRB through The University of Montana Research Office at 243-6670.

Statement of Consent: I have read the above description of this research study. I have been informed of the risks and benefits involved, and all my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions I may have will also be answered by a member of the research team. I voluntarily agree to take part in this study. I understand I will receive a copy of this consent form.

_____
Printed (Typed) Name of Subject

_____ _____
Subject's Signature Date

Statement of Consent to be Audiotaped:

I understand that audio-recordings) may be submitted during the study. I consent to use of my audiotape transcript in presentations related to this study. I understand that if transcript of audio recordings are used for presentations of any kind, names or other identifying information will not be associated with them. I understand that audio recordings will be destroyed following transcription, and that no identifying information will be included in the transcription.

_____ _____
Subject's Signature Date

Approval Expires On 10/26/2010
Date Approved By UM IRB 10/27/2009
IRB-Chair

Informed Consent to Audiotape

In order to provide the best practice for you, it is important for me to have good interview/counseling skills when we discuss your health care concerns/behavior change. I am involved in a program where my interview/counseling skills are reviewed in an effort to improve services I offer those who seek services with me.

I would like to ask your permission to allow me to audio tape your interview/counseling time with me. There will be no disclosure of your name in this activity-no one will know your full name.

The tape will be reviewed by me and a supervisor with whom I work with on interviewing/counseling skills. It also may be used in teaching interview skills with your permission (initial here if yes__). Any replay of the tape will not involve disclosure of your identity. Your name and signature below will not be kept with the taped transcript to ensure your privacy.

, _____, allow my interview to be audio taped today and understand the reasons for this request. **I have had my questions concerning this answered and understand that my participation is entirely voluntary. I may revoke this consent at any time by notifying my provider.**

_____ _____

Interviewee Signature (assent if minor, 10-18) **Date**

_____

Name of Interviewee (printed)

_____ _____

Parent or Guardian Signature (if minor) **Date**

Approval Expires On 10/26/2010
Date Approved By UM-IRB 10/27/2009
IRB-Chair

<In an effort to be environmentally responsible, please expand/reduce box size as needed.>

4. Purpose of the Research Project (not to exceed 500 words): Briefly summarize the overall intent of the study. Your target audience is a non-researcher. Include in your description a statement of the objectives and the potential benefit to the study subjects and/or the advancement of your field. **Generally included are literature related to the problem, hypotheses, and discussion of the problem's importance.** Expand box as needed.

Motivational Interviewing Training: A pilot study

Research has demonstrated the efficacy of Motivational Interviewing (MI) (Miller & Rollnick, 2002) in the treatment of a wide range of mental and behavioral health areas seeking to address behavior change (Burke, Arkowitz & Menchola, 2003; Hettema, Steele and Miller, 2005). This includes addictions, psychotherapy, and areas in medical care such as cardiovascular rehabilitation, and diabetes management (Dunn, Deroo, & Rivara, 2001). Randomized controlled clinical trials have been generally, but not always, positive. Analysis of some of these findings has revealed variation in clinician ability to implement Mi effectively (Miller & Rose, 2009). There is evidence to suggest aspects of MI that are essential to practice, may not be delivered appropriately by practitioners (Hettema, et al 2005, Miller & Rose, 2009). Analysis of key skills and implementation of MI reveal that effective delivery is not a simple task, to be dictating the same for each client and includes sensitive delivery of two essential components: relational skills and technical skills, (Madson, Loignon & Lane, 2009). Studies of training practitioners in MI have revealed several important findings. Professionals over-rate their actual skill when a comparison is made between self-report and behavioral observation (coding of audio transcripts), and a standard 2 day training in essential skills does not provide a sufficient venue to acquire skills in community practitioners (Miller et al, 2004). Only with supervised follow-up coaching or feedback did practitioners demonstrate acquiring skills to competency that last beyond a 1 month period (Miller et al 2006).. Although this knowledge is now available, it remains difficult without a funded study to get community practitioners participating in training MI workshops to complete training identified as necessary for competence (Mint Forum, 2009). When trainers from the MINT group of trainers provide community training in naturalistic settings, community practitioners fail to commit to the intensity of training necessary to achieve the level of practice identified as competent (MINT Forum, 2009). This includes two essential features of skill acquisition: 1) follow-up coaching and 2) audiotape scoring and feedback. This study seeks to conduct a naturalistic assessment of training and follow-up of community practitioners from the medical, mental health and justice fields who were recruited to participate specifically in a training that is intensive and will offer the opportunity for learning to competence.

5. IRB Oversight

Is oversight required by other IRB(s) [e.g., tribal, hospital, other university] for this project? ☐Yes X No

If yes, please identify IRB(s):

6. Subject Information:

a. Human Subjects *(identify, include age/gender)*:

Men and women, age 18+ participating in a continuing education training in Motivational Interviewing as a professional in the medical, mental health or justice fields.

b. How many subjects will be included in the study? 100

c. Are minors included *(under age 18, per Montana law)*? ☐ Yes X No

If yes, specify age range: to

d. Are members of a physically, psychologically, or socially vulnerable population being specifically targeting?

☐Yes X No

If yes, please explain why the subjects might be physically, psychologically or socially vulnerable:

e. Are there other special considerations regarding this population? X Yes ☐ No

If yes, please explain:

A second consent form is provided here for clients of the professionals who agree to let the participating professional's audiotape be coded. The tape is coded for therapist behavior not client. However, the client's private information will be on the tape and should be protected information (clients remain anonymous) and the client should consent for the professional to use the interaction.

f. Do subjects reside in a foreign country? ☐ Yes *Specify country* X No

g. How are subjects selected or recruited? What is inclusion/exclusion criteria? *(Attach copies of all flyers, advertisements, etc,. that will be used in the recruitment process as these require UM-IRB approval)*

This is a continuing education offering to professionals in the medical, mental health, and justice fields. They will have been sent a flyer inviting them to participate in the training (see attached). All participants will be offered the opportunity to participate in research on the training process and effects on performance when they arrive at the training event on November 6th prior to the training beginning. Because this is a naturalistic study we do not want to exclude any professional from the training who wishes to participate in the standard format we are offering the training, thus no exclusionary criteria.

h. How will subjects be identified in your personal notes, work papers, or publications: *(may check more than one)*

☐ Identified by name and/or address or other
(Secure written [e.g., ICF] or verbal permission to identify; if risk exists, create a confidentiality plan.)

X☐ Confidentiality Plan (FOR PARTICIPANTS)
(Identity of subjects linked to research, but not specific data [e.g., individuals identified in ICF but not included in publications]; identification key kept separate from data; or, data collected by third party [e.g., Select Survey, SurveyMonkey, etc.] and identifiers not received with data.)

X☐ Never know participant's identity (THIS APPLIES TO CLIENT AUDIOTAPE ONLY)
(An ICF may be unnecessary [e.g, anonymous survey, paper or online] ***unless*** *project is sensitive or involves a vulnerable population.)*

i. Describe the means by which the human subject's personal privacy is to be protected, and the confidentiality of information maintained. If you are using a Confidentiality Plan (as checked above), include in your description a plan for the destruction of materials that could allow identification of individual subjects.

The only difference between the method for those in the study and those who complete the training and are not in the study will be completing written materials and having an id assigned to separate identity from data. Participants in the study will be given identification numbers associated with consent, audiotape, and written materials. Because this is a within subjects design, the id number code will be kept separate from the written materials, but id number will be associated with the same person at time 1 (pre-test), time 2 (post-test), time 3 (1 month), time 4 (3 months), and time 5 (6 months-post). However, all participants in the training whether they participate in the study or not who choose to get audiotape feedback on their skills during follow-up will have tapes associated with their names, and this will also include id, when in the study. As a study of the naturalistic process of training to competency, it will be important to follow the percentage of participants who choose to engage in each aspect of the training process at each time period. Tapes that are coded will be of professional's talk behavior only. However, clients who will be taped will need to complete a separate consent form allowing their individual session to be coded as part of the study feedback to the participating professional. The client will not be identified, and it is not required to use the same multiple audiotapes. The client is not being studied. The professionals audio files will be submitted to the study team by email and encrypted prior to being sent using Axantum Acrypt. Participants will be given an explanation of the research (see attached) at the beginning of the project. Participants will be sent an email summary of the results after the data is compiled at the end of the study.

j. Will subject(s) receive an explanation of the research – separate from the informed consent form (if applicable) – before and/or after the project? X *(attach copy and explain when given)* ☐ No

7. Information to be Compiled

a. Explain where the study will take place *(physical location not geographic. If permission will be required to use any facilities, indicate those arrangements and attach copies of written permission):*

This study is scheduled to take place at The Doubletree Hotel where the training will be offered on November 6 and 7, 2009 for time 1 and time 2. For times 3 – 5, participants will be allowed to complete the written materials at a place of

their designation. Tapes will be collected by participants at their place of employment with consent of the participating client. They will then be downloaded, encrypted, and sent by email to the graduate assistant for coding. Please see attached MITI coding for information and coding process (Moyers, 2004. Again, whether in the study or not coding and feedback on skills will occur. The written materials compiled will be for study participants only. The time to complete the materials should be approximately 10-15 minutes. To code the audiotape a 20 minute sample interaction is needed to validly score the material.

b. Subject matter or kind(s) of information to be compiled from/about subjects:

We will be examining the participation and acquisition of motivational interviewing skills and the relationship between level of participation in training and commitment to the training process. See measures (attached). These include demographics, pre and post-knowledge, MITI scores of audiotapes, Positive and Negative Affect Scales (PANAS) Watson, Clark & Tellegen, 1988, Perceived Stress Scale(PSS) Cohen & Williamson, 1988. See attached Scales.

c. Activities the subjects will perform and how the subjects will be used. Describe the instrumentation and procedures to be used and kinds of data or information to be gathered. **Provide enough detail** so the IRB will be able to evaluate the intrusion from the subject's perspective (expand box as needed):

Participants will be involved in a 2-day training in motivational interviewing skills. They will complete the written measures (Listed above and attached) if they consent to participate in the study at times 1-time 5. Participants who choose to be involved in follow-up and submit audiotapes will have their tapes scored according to the MITI coding system and receive feedback on their performance from one of the PIs. MITI codes Collaboration, Evocation, Autonomy/Support, on a rating scale of 1 to 5 and these data points will be stored in the data set.

d. Is information on any of the following included? *(check all that apply)*:

- ☐ Sexual behavior
- ☐ Drug use/abuse
- ☐ Alcohol use/abuse
- ☐ Illegal conduct
- ☐ Information about the subject that, if it became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability.

e. Means of obtaining the information *(check all that apply)*. **Attach questionnaire or survey instrument**, if used:

- ☐ Field/Laboratory observation
- ☐ Blood/Tissue/Urine/Feces/Semen/Saliva Sampling *(IBC Application must be submitted)*
- ☐ Medical records *(require HIPAA form)*
- X Measurement of motions/actions
- ☐ Use of standard educational tests, etc.
- ☐ Other means *(specify)*:
- X In-person interviews/survey
- ☐ Telephone interviews/survey
- *X* On-site survey
- ☐ Mail survey
- ☐ Online survey *(attach Statement of Confidentiality)*
- ☐ Examine public documents, records, data, etc.
- ☐ Examine private documents, records, data, etc.

f. Will subjects be *(check all that apply)*:

☐ Videotaped X Audio-taped ☐ Photographed ☐ N/A

(securing an additional signature is recommended on consent/assent/permission forms)

Explain how above media will be used, who will transcribe, and how/when destroyed:

Participants who choose to receive audiotape feedback will send the audio file after it is encrypted by email to the graduate student for coding. Once scored the audio record scores will be kept for data analysis. The audio record may be used for feedback during the follow-up portion and may become a part of ongoing training if the participant and client agree to this specific use of the transcript only. Otherwise, the audiotape scores will be stored according and disassociated from any identifying participant.

g. Discuss the benefits (does not include payment for participation) of the research, if any, to the human subjects and to scientific knowledge *(if the subjects will not benefit from their participation, so state)*:

Although there are no direct benefits to participating in this study or not. Knowledge and dissemination of empirically supported treatments (ESTs) are essential to scientific and responsible practice in the medical, mental health and juvenile justice fields. Studies have established Motivational Interviewing (MI) as an empirically supported treatment and have also contributed to our knowledge of essential training methodology for effectiveness, dissemination to community practitioners who then practice competently has been elusive. This study will be a naturalistic examination of training dissemination that seeks to examine whether advertising for the opportunity to be trained to competence increases the likelihood of participants who are committed to full participation in the recommended methodology and assessment. Participants will have an opportunity to contribute to the scientific knowledge base on dissemination of

ESTs using a scientifically responsible and rigorous approach to training community practitioners rarely available. All attendees will be trained by Motivational Interviewing Network Trainers (MINT) in a local setting with the choice of follow-up venue (local supervision group, computerized live interaction and feedback or phone coaching). Those who choose to participate in the study will contribute to the scientific understanding of treatment dissemination.

h. Cite any payment for participation (payment is not considered a benefit):

No payment will be given for participation.

i. Outline, **in detail**, the risks and discomforts, if any, to which the human subjects will be exposed *(Such deleterious effects may be physical, psychological, professional, financial, legal, spiritual, or cultural. As a result, one can never guarantee that there are no risks – use "minimal." Some research involves violations of normal expectations, rather than risks or discomforts; such violations, if any, should be specified)*:

This study is expected to have minimal discomfort. Those who choose to participate in this study will experience no greater discomfort than those who do not except that which might be associated with answering the written measures about motivation for training. The training will involve role playing scenarios that sometimes create emotional discomfort in participants who are shy about displaying skills publicly. Audiotaping and feedback on skill acquisition is much like taking an exam and can be uncomfortable especially if the feedback is not positive. Answering questions about knowledge, motivation, affect and stress may evoke uncomfortable feelings.

j. Describe, **in detail**, the means taken to minimize each such deleterious effect or violation::

Opting out of role plays is always an option and participants will choose their level of feedback for follow-up. Verbal feedback, when given will be strengths-based and focus on potential for improvement.

8. Informed Consent

An informed consent form (ICF) is usually required, unless subjects remain anonymous or a waiver is otherwise justified below. *(Templates and examples of Informed Consent, Parental Permission, and Child's Assent Forms are available at* http://www.umt.edu/research/complianceinfo/irb/forms.aspx).

- A copy of the consent/assent/permission form **must be offered to all subjects**, including parents/guardians of subjects less than 18 years of age (minors).
- Use of minors
    - All minor subjects (under the age of 18) must have written parental or custodial permission (45 CFR 46.116(b)).
    - All minors from 10 to 18 years of age are required to give written assent (45 CFR 46.408(a)).
    - Assent by minor subjects: All minor subjects are to be given a clear and complete picture of the research they are being asked to engage in, together with its attendant risks and benefits, as their developmental status and competence will allow them to understand.
    - Minors less than 10 years of age and all individuals, regardless of age, with delayed cognitive functioning (or with communication skills that make expressive responses unreliable) will be denied involvement in any research that does not provide a benefit/risk advantage.
        - Good faith efforts must be made to assess the actual level of competence of minor subjects where there is doubt.
        - The Minor Assent Form must be written at a level that can be understood by the minor, and/or read to them at an age-appropriate level in order to secure verbal assent.
- Is a written informed consent form being used? X Yes *(attach copy)* ☐ No *(justify below)*

  To waive the requirement for written informed consent (45 CFR 46.117), describe your justification:
- Is a written parental permission form being used? X☐ Yes *(attach copy)* ☐No

  (If yes, will likely require minor assent form)
- Is a written minor assent form being used? X☐ Yes *(attach copy)* ☐No

  (If yes, will likely require parental permission form)

The Principal Investigator agrees to comply with all requirements of The University of Montana-Missoula IRB, the U.S. Department of Health and Human Services Office of Human Research Protection Guidelines, and NIH Guidelines. The PI agrees

to ensure all members of his/her team are familiar with the requirements and risks of this project, and will complete the Human Subject Protection Course available at http://www.umt.edu/research/complianceinfo/irb.

Principal Investigator's Statement

I certify that the statements made in this request are accurate and complete. I also agree to the following:

- If I receive approval for this research project, I agree to inform the IRB in writing of any emergent problems. I further agree not to proceed with the project until the problems have been resolved.
- I will not make any significant procedural changes to procedures involving human subjects without submitting a written amendment to the IRB and will not undertake such changes until the IRB has reviewed and approved them.
- It is my responsibility to ensure that every person working with the human subjects is appropriately trained.
- I will not begin work on the procedures described in this protocol until I receive notice of approval from the IRB.
- I will keep a copy of this protocol (including all consent forms, questionnaires, and recruitment flyers) and all subsequent correspondence.

Signature of Principal Investigator: _____ Date: _____

NOTE: I AM AWARE that electronic submission of this form from my University email account constitutes my signature.