Department of Psychiatry

Final Report

Dr. Mark Paller, Interim Head, Department of Psychiatry

June 30, 2016

The Department of Psychiatry has been a key focus of the University’s work to Advance Human Research Protections. Over the past year of this work, the faculty and staff in the department have embraced the change and improvements proposed and have gone above and beyond what has been requested of them. They have embraced a new culture of transparency and collaboration and have been working with the Clinical Translational Science Institute to institute Good Clinical Practices. They have welcomed additional monitoring and project management support of trials and passed several new policies to enhance the ethics and quality of their work. The Department’s research council has also had several meetings with the Center for Bioethics to discuss consent and other issues.

The Department’s culture has already begun to shift under new leadership, and the faculty look forward to the new permanent head starting this summer. Dr. Sophia Vinogradov is an accomplished researcher, clinician and leader and will help move the work of the faculty and staff forward. She has already begun meeting with stakeholders in the department and the community and will be a major step forward for our work in this important area.

This report will share specifically the accomplishments made in response to the Implementation Team report, approved by the Regents on June 12, 2015. Following that approval Dr. Mark Paller was charged by President Kaler to led the implementation of the recommendations for the Department of Psychiatry.

In order to address the ongoing criticism of the department’s culture and practices, the Implementation Team focused on:

- CTSI management of interventional drug and device trials in the Department of Psychiatry
- Education and training for investigators and research staff
- Training for investigators and research staff specific to clinical research with individuals who have impaired or fluctuating capacity to consent
- A specific IRB panel with specialized training on the unique needs of vulnerable individuals
- Climate assessment
- Enhancing a culture of mutual trust between clinical care and research
- Enhanced research training and oversight of two investigators
CTSI Management

As of July 1, 2016 CTSI will manage human participant trials in the Department of Psychiatry. CTSI has already been working with investigators and staff for several months, and the team feels that there has been a great deal of progress in understanding and implementing Good Clinical Practices.

CTSI is currently searching for both a Psychiatry Department Clinical Research manager and a Regulatory Specialist for the department, individuals who will be responsible for overseeing the management of human subject research for the department. Until the positions are filled, CTSI’s Lead Clinical Research Advisor and one of the Regulatory Specialists from CTSI’s Research Services team will support Psychiatry research and student personnel. In addition, CTSI monitors are starting to monitor additional studies in the Psychiatry research portfolio. (full plan attached) CTSI has engaged new head Dr. Sophia Vinogradov in this work.

Kelvin Lim, Vice Chair for Research, is co-owner, along with Susan Craddock of the Center for Bioethics, of a new course being developed by CTSI entitled Good Clinical Practices: The Informed Consent Process. This training will begin as a pilot in Psychiatry in late August. (description attached)

In addition, investigators in the department have started moving their trials to the OnCore Clinical Trials Management system, and CTSI’s Clinical Trials Financial Services team is providing financial management for Psychiatry trials. Faculty are supportive of, and fully engaged in, the transition to CTSI oversight.

Education and Training

The Department will take part in all training required by the new AHRP Education Advisory Group which will be run by and report to OVPR. The Department also plans to participate in that group as requested.

Impaired or fluctuating consent

The Department is working closely with HRPP to implement new policies and training in this area and is serving as a pilot to test the new tools being proposed in the proposed new policy.

IRB panels

The Department has faculty participating in the IRB, in addition to the expertise in this area from outside the University. The department responded to a request from the IRB last year with recommendations for several new members of the IRB.

Climate Assessment

In response to concerns that there was an unproductive and potentially hostile climate between the clinical staff and researchers within behavioral health, several recommendations have been made regarding the assessment and improvement of the culture in the behavioral health unit.

The IRB in 2015 did an investigation into concerns expressed about psychiatric research which has been called the Oakes report. That report found a level of mistrust and misunderstanding between clinical
staff and researchers, but no specific examples of non-compliance. A follow-up climate assessment will be conducted by Fairview Research Services with oversight from FUROC.

In addition, Dr. Vinogradov is undertaking a comprehensive strategic planning process for the Department and its clinical partners within University of Minnesota Physicians, University of Minnesota Health, and Fairview Health Services. Part of this process will be a comprehensive environmental assessment for the department and clinical units.

**Culture of inclusion**

The Department took very seriously the need to improve communication and collaboration with clinical staff at Fairview. In November 2015 they convened a joint Fairview Behavioral Health and UMN Department of Psychiatry committee to develop policies and procedures for systematically obtaining clinical staff input on psychiatry clinical research projects prior to IRB submission and again following IRB approval. The checklist (attached) has been implemented to a positive response and may possibly be used for other areas of research as well. Monitoring compliance with this process will be the responsibility of the Clinical Research Manager.

**Two Investigators**

The external review focused specifically on two researchers in the Department of Psychiatry who have received ongoing criticism. The implementation team recommended that they received supervision, coaching and advanced training in human participant protections. The team also recommended more enhanced monitoring for clinical research protocols they participate in and that they attend the OVPR symposium on human research participant ethics.

One of those researchers has retired and is no longer a member of the department or University faculty. The other is not currently participating in research but fully understands the requirements if he chooses to reengage (memo attached). He did attend the ethics conference in December 2015.

**Additional information**

The Department has instituted a new policy to mitigate issues of therapeutic misconception. Going forward, an investigator who is also a treating physician should not be involved in the consenting process (memo attached). It is important to note that this change was not required by the University but is something the Department chose to do, with the support of the Medical School and the University.

**Conclusion**

The culture and practices in the Department of Psychiatry have and are continuing to improve. The faculty and staff have embraced change and will continue to participate in new required and recommended processes in order to maintain the highest levels of ethics and research. The steps recommended by the Implementation Team are complete or near it, however, maintaining high standards will be ongoing work for the department, the Medical School and the University.
Department of Psychiatry Human Research
Management Plan for July 1, 2016

Personnel Assigned: CTSI will assign 2.0 FTE to Psychiatry effective July 1, 2016

- Anne Hopper, CTSI’s Lead Clinical Research Advisor, will be in the Psychiatry department 20 hours a week, until the time that the Psychiatry Clinical Research Manager is hired/on board.
- A Regulatory Specialist (TBA), will be in the Psychiatry department 20 hours per week, until the time that the Regulatory Specialist for Psychiatry is hired/on board.
- A Clinical Research Associate (aka Monitor) will begin monitoring all research involving humans, following the attached monitoring plan (see page 4-5).
- Jennifer Maas, RN, a Clinical Research Preceptor, will begin in-person clinical research training and education on August 1, 2016, increasing the FTE effort from the original 2.0 FTE assigned. Group in-person sessions are open to both investigators and research staff, while the individualized training/education is targeted to the research staff.

Management Activities:

- CTSI’s Workforce Manager is in contact with the Human Research team for Psychiatry to ensure a complete listing of all staff in the of Psychiatry who support human research.
- A departmental email account to support research management has been established (psychrsh@umn.edu) and all studies will be required to submit an Add/Change personnel form to the IRB no later than Friday, July 8, 2016, adding psychrsh@umn.edu as a correspondent on the study.
- Working with investigators and study teams, a listing of all active Psychiatry human research studies (excluding studies in data analysis only) will be confirmed (between July 1-8) and beginning the week of July 11, project status update meetings will be conducted by the CTSI team, on an every other week basis. A representative from each study will be required to attend these weekly meetings and report the current status of the study.
  - Data items updated weekly include:
    - Status (new, enrolling, closed to enrollment, hold, etc.)
    - Regulatory/IRB updates (including any upcoming monitoring visits)
    - Overall study issues/concerns if any
    - Recruitment updates
    - Anticipated start
    - Anticipated close
    - Enrollment goal
    - # consented
    - # screen fail
    - # randomized
    - # completed
    - Date closed
These meetings will also serve as an opportunity for study staff to ask questions and share insights regarding their studies and serve as a venue to facilitate awareness of other research activities and share expertise with colleagues.

In between the weekly meetings, Anne Hopper and the Regulatory Specialist will follow-up with study staff who have questions, identify issues, or need guidance on studies.

- Investigators and study teams will be required to inform psychrsh@umn.edu (at a minimum) as planning for new studies begins. Once informed, the CTSI staff will assist with navigating the various research systems (OnCore, Clinical Trials Financial Services, Fairview Research Administration), answering questions, and providing guidance.
- Additionally, Anne and the Regulatory Specialist are available to assist investigators and staff with study questions, navigation of the research environment, etc.
- As studies are monitored, a copy of the monitoring report will be shared with the CTSI management group, so they are able to follow-up and assist with resolving findings. In addition, the Monitor is available to offer guidance to the study teams, as questions related to the monitoring visits arise.
- In early July, Psychiatry Research Staff will be asked to complete the new HIPAA course (HIPAA 16 - HIPAA Training, available through U Learn), if it isn’t already complete. Additionally, staff will be asked to confirm that their CITI Basic course training is up to date (available through CITI; sign in through the “Log in through my institution” section on the right side). The requirement will be that these two trainings are complete no later than July 31, 2016.
- During the middle of July, CTSI’s Workforce Development team will conduct a proctored Clinical Research Coordinator competency-based assessment, which will serve as the basis for providing in-person group and individual educational and training activities.
- After the proctored assessment, staff will be informed of the requirement to complete both the online Clinical Research Coordinator training program and CITI’s Good Clinical Practice (GCP) course prior to August 15, 2016.
  - Topics included in the Clinical Research Coordinator training program training program include:
    - Non-Fairview Employed Research Staff (NERS) (as required)
    - Research 101 for Clinical Research Coordinators (offers certificate of completion)
    - Bloodborne Pathogens
    - Good Clinical Practice
    - Hazardous Material Shipping
    - Navigating Research at the University of Minnesota
    - Research Ethics (offers certificate of completion)
    - Role of CRC Certification (offers certificate of completion)
    - University of Minnesota and Fairview Research Policies (offers certificate of completion)
    - Participant Recruitment and Retention
- Beginning in August 2016, Jennifer Maas will conduct in-person group training sessions, where the topics will be based on the results of the Clinical Research Coordinator
assessment. These sessions will focus on the work of the research staff, but all investigators will be informed of the sessions and invited to attend.

- As new training sessions are developed and offered by HRPP (or others) on topics such as new policies or the capacity to consent, the CTSI team will ensure that investigators and study team members are aware of the sessions and will be strongly encouraged to attend.

- In late August, the *Good Clinical Practices: The Informed Consent Process* course will begin as a pilot for Psychiatry investigators and study staff.

- All research staff will be added to the CRC listserv managed by the CTSI, and will be strongly encouraged to attend the bi-weekly *Clinical Research Professional Development Series*.

- A proctored post-assessment will be administered upon completion of the training program to ensure all competencies have been met.
PSYCHIATRY MONITORING PLAN
(for studies that are not a part of the current CTSI Monitoring Program)

Step 1.

Meet with each investigator and coordinator to do “a pre-monitoring visit”.

At this visit, the monitor will review regulatory binder requirements, case report form completion, and IRB and GCP requirements with the investigator and study team.

Set up first monitoring visit for 3 weeks from date to review regulatory binder and any subject data if applicable.

Step 2.

3 weeks after start up visit, first monitoring visit will take place.

After completing monitoring visit and reviewing with coordinator and PI the items that require prompt attention. Prompt attention items are items deemed critical to the study conduct or subject safety (if any), see examples below. If the study has items that need prompt attention follow-up review visits will be scheduled at 3-week intervals until all items are completed. If the study does not have any items that require prompt attention, a review visit will be scheduled for 6 weeks after first visit.

If prompt attention items are not completed after 3 weeks, monitor will use the CTSI monitoring escalation plan.

Step 3.

Once study has been monitored two consecutive times and does not have any major findings (prompt attentions items) we will put it on a 6-month visit schedule.
Items requiring *Prompt Attention* (including but not limited to):

**Consent issues:**
Wrong version consent signed  
Consent process not documented  
Missing signatures or signature dates  
No consent for subjects

**HIPAA:**
No HIPAA forms signed or missing forms

**Data Issues:**
Missing data on CRF’s that are primary endpoints  
SAE’s not reported  
Signature logs not complete for who can consent

**Enrollment:**
Ineligible subjects enrolled  
Subject eligibility not documented  
Improper recruitment of study subjects

**Protocol compliance:**
Missed assessments that affect subject safety or study objectives
Good Clinical Practices: The Informed Consent Process

Background and Purpose

Recommendations from two 2015 External Reviews of clinical research at the University of Minnesota defined some priorities for the training and education of investigators, research coordinators, and research staff. Priority training needs include:

• Good Clinical Practices
• Reporting of adverse events and protocol deviations
• Source Documentation
• Documentation of informed consent
• Inclusion/exclusion criteria assessment prior to consenting
• Safety monitoring.

Concurrent to the University of Minnesota reviews, in 2014 - 2015, the National Center for Advancing Translational sciences (NCATS) sponsored a national task force initiative, Enhancing Clinical Research Professionals’ Training and Qualification (ECRPTQ). The purpose of that project is to ‘improve the efficiency, safety, and quality of clinical research, as well as reduce redundant training requirements.’ To date, the task force has delivered two products to NCATS for approval: 1) recommendations for a national mandate that all study personnel engaged in drug, device, biologic, and/or behavioral intervention studies should receive GCP training, and 2) minimal competencies necessary for research personnel to execute safe, high quality, and efficient clinical trials, the definition of which will serve as the basis for the development of a training approach to teach and assess those competencies.

The Education and Training component of the University’s Advancing Human Research Protections Implementation Team is in the process of evaluating current training resources and identifying priority areas of needed enhancement. Within the context of that larger process, we will begin to upgrade training in the most critical areas of need by developing competency-based, hybrid-format programs for investigators and research teams. The University already offers a number of good knowledge-based training programs—including a semester-long Standards for Research with Human Participants course, ongoing IRB and CTSI presentations, The Clinical Research Coordinators Orientation curriculum, and the CITI basic training course—on which to base additional skill-building and application courses. It has been recommended that new training programs will be pilot-tested within the Department of Psychiatry.

Based upon the priorities outlined in the external reviews, this proposal outlines the first course to be developed and piloted within the Department of Psychiatry: Good Clinical Practices: The Informed Consent Process. The general scope of that course will include:

• Basic concepts and definitions, such as vulnerable populations, therapeutic misconception, and coercion
• Best recruiting practices
• Informed consent plans (PI) – ICH6
• Writing of forms (to appropriate grade level)
• Documentation of informed consent
• Documentation of inclusion/exclusion criteria assessment prior to consenting
• Protection of Privacy requirements
• Conducting an ongoing consent process throughout a research study for vulnerable participants and/or those with diminished and/or fluctuating decision-making capacity (including the legal use of surrogate decision-makers)
The Need: Quality Learning Programs and Environments

Educational theory has long held that knowledge-based learning is insufficient to ensure the development of skills and attitudes required to demonstrate basic competence and sustained performance. Yet, the learning objectives of the University’s current Informed Consent modules in the Basic course (CITI) offer learning objectives (followed by multiple choice questions) that are inadequate to fully equip all research personnel with an understanding of what constitutes good clinical practices and adequate, appropriate protection of human participants in clinical trials.

Learning Objectives: By the end of the module you should be able to:
- **Describe** the requirements for complying with informed consent regulations.
- **Describe** the process for obtaining informed consent.
- **Define** vulnerable populations
- **Describe** the regulations for waiving informed consent.

(The five learning outcomes from the GCP course, Informed Consent in Clinical Trials of Drugs, Biologics, and Devices are a slight variation on this theme.)

When printed, the basic Informed Consent module consists of a little over four pages (including references and resources).

Although CITI courses and modules are a national standard used to train the many busy investigators and research staff in this country, relying solely on online modules characterized by multiple choice questions accompanied by only basic explanations is contributing to the challenges that the University is experiencing with the quality of our human subjects research. After taking the five minutes it took to complete this Informed Consent module and receiving a score of 100%, I do not feel that I know the regulations guiding informed consent (nor exactly where to find them as reference), could not set up or manage the process in a clinical study, and certainly did not have a chance to experience the underlying values critical to conducting safe clinical trials, nor to internalize the importance of this procedure within the context of the ethical conduct of research.

Quite simply, this ‘get it done as quickly as possible’ read-through of the CITI Informed Consent module did not constitute a meaningful learning opportunity.

Why? Basic learning theory and principles offer multiple explanations. Consider the CITI module learning outcomes and assessment described above against the learning frameworks summarized below. In every case, the CITI module addresses only the lowest levels of thinking and learning within each model.

**Bloom’s Revised Taxonomy of Cognitive Levels**

Benjamin Bloom’s definition of levels of thinking build in upward order of difficulty, from basic memorization to high orders of critical thinking skills. Since the 1950’s, educators have used Bloom’s taxonomy of learning objectives as a guideline for the purposeful design of learning based on the needs of the target learners.
Kirkpatrick’s Evaluation Framework
Also in the 1950’s, Donald Kirkpatrick developed a training evaluation model to measure the effectiveness of training based on four levels: 1) reaction, 2) learning, 3) behavior, and 4) results. As he continued to revise the model in later years, using it as a standard for defining measurable learning outcomes, Kirkpatrick continued to postulate the highest form of learning outcome to be performance. In 2015, Kirkpatrick’s model was adapted into the following framework, which stipulates performance outcomes related to change in practice as well as impact on patients, families, and communities in the context of interprofessional clinical care. This model can also be applied to the design of training and education in clinical research.

- Level 1a: Learner’s reaction
- Level 2a: Modification of attitudes/perception
- Level 2b: Acquisition of knowledge and/or skills
- Level 3: Behavioral change
- Level 4a: Change in organizational practice
- Level 4b: Benefits to patients or clients

Miller’s Pyramid of Assessment
Developed for the purpose of assessing clinical skills, George Miller, MD, developed a now commonly used framework for designing and measuring competence and performance of medical cognition and behavior:
Learning and Performance Ecosystems

Current constructs from the world of learning and learning organization design suggest that successful learning occurs within settings in which learning is both formal and informal, structured and self-directed, and supported at the moment-of-need in order to promote effective performance.

This would suggest, for example, that investigators and research teams not only be provided programs to learn knowledge, skills, attitudes, achieve competence, and demonstrate performance, but also ongoing access to experts, best-practice resources, and peer-learning at the point of need in the process of implementing their clinical studies.

The University of Minnesota is not only a research institution, but also an educational institution. What is being suggested in this proposal is that it is time to re-examine the training programs currently being offered to investigators and the research workforce, and ensure that those programs provide more than just easy and rapid access to the most basic baseline of knowledge about research with human participants. Instead, we need to seriously address how to design, deliver, evaluate, and create a culture that supports exemplary learning programs that provide knowledge of how to conduct human research studies and offer practice in skillful clinical study management. Such learning programs require learner-centered activities and simulated decision-making about ethical issues that comprise the challenges of real-world research with human subjects.

**Audiences**
The proposed training program, *Good Clinical Practices: The Informed Consent Process*, will be designed so that it can be flexibly used to train investigators as well as research coordinators and staff. The initial pilot of the program will be offered to Department of Psychiatry research coordinators and staff as well as faculty who wish to attend. To the degree possible, we intend to develop the course so that it can be adapted to the needs of researchers conducting various types of research, for example, social-behavioral research, for which a shortened version may be appropriate. The course also offers an opportunity for the Post Approval Review program to leverage the course to educate investigators who are non-compliant with consent regulations.

**Preliminary Goals and Learning Outcomes**
The overarching goal for course participants is to:

> Confidently, ethically, and humanely carry out all tasks appropriate to their roles within the research team in the informed consent process for regular and special populations of participants according to the FDA 21CFR 50.25 and 45CFR46.111 requirements, ICH GCP principles and Good Clinical Practice guidelines, Minnesota Law, and University of Minnesota guidelines.

Possible learning outcomes:
By completing the training, participants will be able to:

- Demonstrate a general understanding of and the capacity to appropriately use as reference 21 CFR 50.25 and 45CFR46.111 requirements, GCP Guideline 4.8: Informed Consent of Subjects, and U of M IRB guidelines (including 2016 guidelines and templates) to carry out their specific research tasks
- Demonstrate an ongoing awareness of and ability to use as guideposts key concepts such as therapeutic misconception and coercion, and the differentiation of goals between research and care
- As such, to utilize recruitment strategies that do not breech conflict of interest (such as physicians recruiting their own patients) or therapeutic misconception arenas.
- Evaluate the general quality and completeness of an informed consent plan, including all required documentation throughout the process as well as adherence to privacy requirements
- Implement strategies to develop consent forms—adapted from standardized templates—that are appropriate to specific research participants
- Demonstrate correct and appropriate conduct of the consent process throughout a research study, including documentation of inclusion/exclusion assessment prior to consenting, protection of vulnerable populations and/or studies with individuals with diminished and/or fluctuating decision-making capacity (including the legal use of surrogate decision-makers, and strategies for protection of privacy). (For example, in therapeutic research, ensure that participants can describe what will happen in research vs what will happen in clinical care for their condition.)
- Consider the topic, locus, and culture of each research study and its participants, and—while maintaining consistent ethical standards—adapt the informed consent process appropriately
• In the case of real-world challenges and ‘grey areas’ that investigators and research teams encounter in the informed consent process, to reflect upon and generate solutions that are positive for human participants while maintaining study goals.
• Demonstrate methods to evaluate and ensure that the consent process has been understood by and has been beneficial to research participants.

We might also consider integrating competencies from the **NCATS/ECRPSTQ domains and competencies**:

- **Ethical & Participant Safety Considerations**:
  - Apply relevant principles of human subject protections and privacy throughout all stages of a clinical trial
  - Define vulnerable populations and additional safeguards needed for protection of those populations
  - Explain how inclusion and exclusion criteria are included in a clinical trial protocol to assure human subject protection
- **Study and Site Management**:
  - Develop strategies to manage participant recruitment, study activities, and track progress
- **Leadership, Professionalism, and Team Science**
  - Identify, analyze, and address ethical and professional conflicts associated with the conduct of clinical trials, in particular, the informed consent process
  - Identify and apply professional guidelines and codes of ethics as they relate to the conduct of clinical trials, in particular, the informed consent process
  - Recognize the potential effects of cultural diversity and the need for cultural competence in the design and conduct of clinical trials

**Description of the Course**

The blended format for the Informed Consent Course for research staff may include online pre-work and two two-hour in-person workshops in which participants will work as large and small groups to complete a variety of activities. IRB personnel and research experts will be invited to participate in the facilitation of the face-to-face workshops. If possible, a community member who has participated in research and/or served as an LAR will be invited to lead a pertinent part of the program. Learners will be encouraged to bring mobile devices (e.g., laptops or tablets) to use throughout the workshop sessions in order to more easily familiarize themselves with informed consent resources.

Possible topics, activities, and formats for the course follow, and will be designed to support the achievement of the suggested learning outcomes. It is likely that a shorter version, possibly with less in-person practice, will be configured for investigators. Also, versions for specific types of research that may not require as much in-depth study and practice can be configured as needed.

Examples, scenarios, and quotations from community participant focus groups will be integrated throughout the online modules and the workshops. One or two participants will be invited to participate in a panel in the first workshop.
### Session 1 Pre-Work  40 minutes seat time: 2 modules

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<th>Topics/Content</th>
<th>Activity Ideas</th>
<th>Formats/Media</th>
<th>Time</th>
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<tr>
<td>Informed Consent Guidelines</td>
<td>• Conduct a ‘scavenger hunt’ (finding specific information per questions and cases) referring to online resources that may include: o CITI GCP Basic Informed Consent module that covers 45CFR46.116(a) and 21CFR50.25(a) (if we can get access for learners just for that module or a couple preceding it and not require completion of the quizzes) o Belmont Report and Declaration of Helsinki o Overview of GCP 4.8 using the University’s GCP course at ctsieducation.umn.edu o Guidelines regarding U of M requirements and IRB preferences at: <a href="http://www.research.umn.edu/irb/guidance/consent.html">www.research.umn.edu/irb/guidance/consent.html</a> and <a href="http://www.research.umn.edu/irb/guidance/guide4.html">http://www.research.umn.edu/irb/guidance/guide4.html</a></td>
<td>• Learners will be directed to a course webpage from which they can download the pdf questions and case assignment questions • Learners can bring completed assignments on a mobile device or in print form</td>
<td>15 - 20 minutes</td>
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<tr>
<td>Informed Consent: Key Concepts</td>
<td>• Key definitions, concepts, and examples of therapeutic misconception, coercion, vulnerable populations, capacity to consent, assent and consent, etc. • References to the SOP Definition Library and HRPP Policies</td>
<td>• Use portions of existing modules such as “Integrating Research into Clinical Environments • Include first-hand reports and examples from research participants</td>
<td>15 – 20 minutes</td>
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### Session 1

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<tr>
<td>Overview and Context-Setting of Informed Consent</td>
<td>• IRB expert provides overview of Informed Consent planning and IRB review and approval process regarding content of consent plans. Includes: o Differences between and preferences for use of GCP Reg. 4.8 and FDA 21 CFR 50.25 o Common areas of need found by the IRB with U of M protocol/informed consent submittals o Informed consent is an ongoing process; commitment to keep participants informed o Roles and responsibilities on the team</td>
<td>• Presentation with demonstration of where to find resources online</td>
<td>15 minutes</td>
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<tr>
<td>Introduction and Stage Setting</td>
<td>• Placing the Informed Consent process within the ethical framework of the Belmont Report and Respect for persons • Integrate ethical recruitment strategies from the outset • Therapeutic misconception/ensuring that participants can describe the target outcomes of the research as well as what will happen</td>
<td>• Large group • Review in small groups</td>
<td>15 minutes</td>
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Good Clinical Practices: The Informed Consent Process
Preliminary Course Design
June 24, 2016
with clinical care pertaining to their condition
- Quick exercise to apply key content – demonstrate one standard but some adaptation based on type of study

| Preparing the Informed Consent Form | • Referring to handouts/links from the GCP course and the IRB website, the IRB representative provides an overview of effective consent forms and refers to new University templates
  • Overview of language for the consent process
  • In small groups, learners evaluate strengths of example consent forms, and how they might be improved for specific audiences (e.g., word choices, graphics, etc.)
  • IRB representative leads large group debrief. | • Large group presentation
  • Small group work and large group debrief (University’s GCP course contains good suggestions/handouts for this) | 30 minutes |

| The Informed Consent Process: Good Practice Strategies | • Small panel of research manager or coordinator and, optimally, one or two participants who have participated in clinical trials present good practice strategies of the consent process (e.g., response to non-verbal cues, good questions to ask, participant explanation of study)
  • Video ‘critique’ in large group with responses from panel
    o Include specific discussion of protection of privacy requirements and strategies throughout the process
    o Discussion of participants or witness signatures
  • Q&A from the large group | • Realistic video presentation of one or two individuals being consented
  • Possibly checklist of good practice informed consent strategies
  • Panel discussion regarding the video
  • Include new materials such as Participant Contact Card, Bill of Rights, Core Commitments | 45 minutes |

| Evaluating and ensuring an ethical and high quality consent process | • Small group discussion about how to obtain feedback from participants to ensure their ongoing understanding of the study and their role as well as their comfort in participating
  • Large group report out and summary | • Small groups discuss strategies for obtaining ongoing feedback from participants regarding their understanding of and comfort with the study | 15 minutes |

| Commitment to change | • Individuals suggest one or two ‘take-aways’ that they plan to implement
  • Session summary and conclusion | • Large group
  • Summary handout of ‘To Do’s and Not To Do’s’ in the informed consent process | 15 minutes |
### Session 2 Pre-Work

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| Ethical Recruitment and Informed Consent of Special Populations and in Special Circumstances | • Online module summarizing regulations and guidelines for recruitment and consent in:  
  o Research with vulnerable populations  
  o Research with participants with diminished or fluctuating decision-making capacity  
  o Emergency situations  
  o International studies  
  o ADA populations  
  o ESL and non-literature populations  
  • New policies (Courtney)  
  • Assent  
  • Translated Short Forms and federal requirements  
  • Perhaps use the University’s module, *Integrating Research into Clinical Environments*, and provide learners overview of research vs care (therapeutic misconception; benefits of research, etc.) | • Create a short module based on/adapting the ‘Communicating with Patients’ section of the *Intro to Translational Research* module that focuses on special populations | 20 minutes    |

### Session 2

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| Informed Consent of Special Populations and in Special Circumstances         | • Apply what’s been learned in a presentation and discussion of cases that illustrate definitions of, challenges, and concerns for vulnerable populations, individuals with limited and/or fluctuating capacity for decision-making, or other specific scenarios such as different (i.e., nonwestern) understandings of consent, consent across geographies, language or disabilities challenges, emergency situations, etc.  
  • Assessing capacity to consent  
  • Discussion of strategies for ongoing consent process throughout a study | • Small group discussions of a series of cases  
  • Large group report-outs from individual groups of their cases (peer-learning)  
  • New materials: SOPs, worksheets, checklists for consent/assent/LAR | 30 minutes    |

| Informed Consent Documentation                                                | • Interactive presentation of the regulations and good practices pertaining to documentation, such as:  
  o Documentation of inclusion/exclusion criteria after consent is signed  
  o Documentation that participants must receive  
  o New information requiring update of a written informed consent form  
  o Documentation of consent in source document such as the participant’s medical record  
  o Signatures and dating of informed consent with special populations, including | • Interactive PowerPoint or presentation of situations in which learners suggest requirements and sources for those requirements | 20 minutes    |
witnesses or LAR
• How do you find and use the correct version?
• Staying organized by integrating OnCore
• Sharing of information post-study closure/ dissemination of results (and sharing incidental findings)

| Rolling Role Play | Small groups are assigned to conduct one part of the consent process for a case that includes:
  o Recruitment check using and documenting inclusion/exclusion criteria
  o Completing the first part of the consent process
  o Consenting at a second visit and/or when new information is available
  o Checking for documentation
  o Introducing new information
  o Obtaining feedback
  o Interpersonal and communication skills | Develop cases and participant descriptions. Facilitators play participants. Small groups are given 5 minutes to plan their section, and 1 member does the role play. Debriefs with the large group ensure key points are addressed
  • Consider Philphott Jones’ SPIKES model (Courtney) | 30 minutes |

| Managing Challenges | Real scenarios are presented in individual slides of events that have challenged the ethical conduct of the consent process. A panel including a department head, IRB expert, investigator, and CRC would be valuable to facilitate the discussion. Roles and responsibilities of investigators, research team members; sources of conflict resolution at the University; negotiating with sponsors resources to refer to should be included. | Panel and large group discussion
  • (Courtney): Identifying non-verbal cues; cultural awareness; handling a ‘pushy’ LAR; potential participant qualifies but concerns exist; PI wants someone enrolled but coordinator doesn’t | 30 minutes |

| Conclusion | Summary
  • Sent as email survey, learner assessment will contain questions about key concepts, some in scenarios. Qualitative information will also be gathered regarding intention and actual application of what was learned.
  • Course evaluation questions will be included in that survey for ongoing quality improvement. | Qualtrics online survey to be sent following course | 5 minutes |
Course Owners
Kelvin Lim and Susan Craddock will serve as the ‘course owners’ or primary stakeholders for this course. Each will provide review/feedback, oversight, and approval of the course throughout and at the end of the development process.

Subject Matter Experts and Consultants
The next step in developing this course and finalizing a plan will be for the instructional designer to convene experts in the Informed Consent process to review and revise this course design, including the planned learning outcomes, content, and suggested formats. The role of the subject matter experts is to determine and provide access to the appropriate content to be learned, reflect the learning styles and format preferences of learners, and review the course as it is developed by the instructional designer to ensure its quality. Subject matter experts/consultants should expect to spend approximately 10 – 12 hours total working on this project over a three—four month timeframe. Subject matter experts may each work on a separate part of the course, so that their time gathering and contributing content will be minimized and not duplicated. The subject matter experts might include the following:

Amanda Galster  Research Support Manager  Dept. of Pediatrics, Medical School
Brenda Prich  Research Support Manager  CTSI
Courtney Jarboe  Education & Outreach Specialist  HRPP/IRB
Jeff Wosniak  Associate Professor  Dept. of Psychiatry, Medical School
Mia Wong  Clinical Research Associate (Monitor)  CTSI Monitoring Team
Sheila Kelleher  Sr. Quality Analyst  HRPP/IRB
TBD  Community Member/Research Participant

Subject matter experts have volunteered to provide content for the following course sections/activities:

<table>
<thead>
<tr>
<th>Section/Activity</th>
<th>Content Expert(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Work Module 1: Informed Consent Guidelines</td>
<td>Courtney Jarboe</td>
</tr>
<tr>
<td>Pre-Work Module 2: Key Concepts</td>
<td>Susan Craddock, Kelvin Lim, Courtney Jarboe</td>
</tr>
<tr>
<td>Session 1: Overview and Context Setting</td>
<td>Amanda Galster</td>
</tr>
<tr>
<td>Session 1: Introduction and Stage Setting</td>
<td>Amanda Galster</td>
</tr>
<tr>
<td>Session 1: Preparing the Informed Consent Form</td>
<td>Courtney Jarboe (Bethany Hansen)</td>
</tr>
<tr>
<td>Session 1: The Informed Consent Process: Good Practice Strategies</td>
<td>Mia Wong, Sheila Kelleher (Bethany Hansen)</td>
</tr>
<tr>
<td>Session 1: Evaluating and Ensuring an Ethical Consent Process</td>
<td>Sheila Kelleher (Bethany Hansen)</td>
</tr>
<tr>
<td>Session 1: Commitment to Change</td>
<td>Janet Shanedling</td>
</tr>
<tr>
<td>Section/Activity</td>
<td>Content Expert(s)</td>
</tr>
<tr>
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</tr>
</tbody>
</table>
| Pre-Work Module 3: Ethical Recruitment... Special Populations | Jeff Wozniak  
Amanda Galster  
Mia Wong  
(Michelle Biros) |
| Session 2: Informed Consent of Special Populations and in Special Circumstances  
• Assessing capacity | Brenda Prich  
Amanda Galster  
Courtney Jarboe |
| Session 2: Informed Consent Documentation             | Brenda Prich  
Amanda Galster |
| Session 2: Rolling Role Play                          | Sheila Kelliher                                             |
| Session 2: Managing Challenges                       | Mia Wong  
Courtney Jarboe  
Sheila Kelleher  
(role plays from Kathryn Sklenar?) |
| Session 2: Conclusion                                | Janet Shanedling                                            |
**Deliverables**

Resources currently available at the University will serve as the basis for enhanced course development. If possible, access for all learner participants to the University’s CITI module, *Informed Consent*, would be optimal. The University’s Good Clinical Practices course—accessible through ctsieducation.umn.edu—may be used for online pre-work, specifically the section: *Investigator Roles and Responsibilities, GCP Guideline 4.8: Informed Consent of Subjects*. IRB sites with guidelines and preferences will be used as well not only for content, but as practice accessing resources for ongoing use. Deliverables for the course will include:

1. **Final design document** (course ‘blueprint’) that will be based upon review of this proposal and collaborative revision with content experts.

2. **Online pre-work/modules**

3. **Web page** with all links and materials for the course, both for participants and for presenters.
   - Assignments and links for Session 1 and Session 2 pre-work
   - ‘Job aids’ and handouts (for example, templates and tips for informed consent forms)
   - Cases and scenarios
   - Agendas
   - GCP, FDA, U of M resources
   - Links to pertinent module sites
   - Interactive space for Q&A

4. **Facilitator Guide**

5. **Learning Assessment and Course Evaluation survey**
   * Documented integration of the competency-based learning assessment items developed for the CTSI Clinical Research Coordinator Orientation in collaboration with Mayo.*
**Development Process**

IRB experts and University and Fairview research personnel (including a Dept. of Psychiatry researcher and possible a coordinator) will be asked to serve as content experts working with the instructional designer(s) to design and develop this course. The inclusion of a community member who has served as or supported a research study participant would also be value for ensuring accuracy, focus on priorities, and credibility of content.

<table>
<thead>
<tr>
<th>Development Activity</th>
<th>Deliverable</th>
<th>Who</th>
<th>When</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Convene subject matter experts</td>
<td>Provide feedback and revisions to the course design</td>
<td>Instructional designer with content experts</td>
<td>June 13, 2016 Complete</td>
</tr>
<tr>
<td>2. Finalize course design</td>
<td>Final course design</td>
<td>Instructional designer</td>
<td>June 27</td>
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<tr>
<td>Stakeholder Review and Approval</td>
<td></td>
<td></td>
<td>July 8</td>
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<tr>
<td>3. Gather content</td>
<td>General ideas, sources, and content</td>
<td>Content experts</td>
<td>By activity/module</td>
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<tr>
<td>4. Group Interviews with Previous Research participants</td>
<td></td>
<td></td>
<td>July 29 – August 7 (Being scheduled)</td>
</tr>
<tr>
<td>5. Develop pre-work cases and assignments</td>
<td><strong>Session 1 Pre-work Module 1:</strong></td>
<td>Instructional designer</td>
<td>Storyboard: July 15</td>
</tr>
<tr>
<td></td>
<td>• Scavenger hunt questions and cases</td>
<td>Content experts</td>
<td>Review: July 22</td>
</tr>
<tr>
<td></td>
<td>• Resources and links to use</td>
<td>Instructional technologist</td>
<td>Finalize: July 29</td>
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<tr>
<td></td>
<td>• Develop course web-page and link to Moodle to track completion and program scavenger hunt</td>
<td>Instructional technologist</td>
<td>Program: 8/12</td>
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<tr>
<td></td>
<td><strong>Session 1 Pre-work Module 2:</strong></td>
<td>Instructional technologist</td>
<td>Storyboard: July 29</td>
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<td></td>
<td>• Design and program 10 – 15 minute module, including activity tracking)</td>
<td>Instructional designer</td>
<td>Review: August 5</td>
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<tr>
<td></td>
<td><strong>Session 2 Pre-work Module:</strong></td>
<td>Instructional designer</td>
<td>Finalize: August 12</td>
</tr>
<tr>
<td></td>
<td>• Interactive online module about special populations and circumstances</td>
<td>Instructional designer</td>
<td>Program: 8/31</td>
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<td></td>
<td>• Self-assessment</td>
<td>Instructional technologist</td>
<td>Storyboard:</td>
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<td>Content experts</td>
<td>Review:</td>
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<td></td>
<td>Finalize:</td>
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<td>9/15</td>
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<tr>
<td>6. Develop Facilitator Guides and Presentation Materials for Session 1 and 2</td>
<td>Facilitator Guides to contain:</td>
<td>Instructional designer</td>
<td>Session 1</td>
</tr>
<tr>
<td></td>
<td>• Agendas</td>
<td>Content experts</td>
<td>Draft 1:</td>
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<td></td>
<td>• Outlines/scripts for each section</td>
<td></td>
<td>7/29</td>
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<td></td>
<td>• Rolling role play (Session #2)</td>
<td></td>
<td>Review:</td>
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<tr>
<td></td>
<td>• Scenarios for discussion of real challenges in studies and guidelines for conducting that discussion</td>
<td></td>
<td>Finalize:</td>
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<td></td>
<td>• Inventory of all participant materials</td>
<td></td>
<td>8/19</td>
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<tr>
<td></td>
<td>• PowerPoints and presentation materials</td>
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<td>Session 2</td>
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<td></td>
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<td>Draft 1:</td>
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<td>9/16</td>
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<tr>
<td>Development Activity</td>
<td>Deliverable</td>
<td>Who</td>
<td>Stakeholder Review and Approval</td>
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</tbody>
</table>
| 7. Create Video of Consenting Process      | Short video with possibly 2 - 3 consenting situations (2-3 minutes each) for critique and discussion in Session 1 | Instructional designer  
Content expert(s)  
Volunteer ‘actors’  
Instructional technologist | Storyboard: July 29  
Review: August 5  
Video Shoot: Aug. 8 – 12  
Edit: August 12 – 25  
Final: August 26       |
| 8. Develop In-person Participant Materials  | • Checklist of good informed consent strategies  
• Small group cases for Session #2 for working with special populations  
• Rolling role play assignment | Instructional designer  
Content experts |                                                   |
| 9. Develop Learner Assessment and Course Evaluation | • Qualtrics Survey | Instructional designer |                                                   |
| 10. Final review of materials for pilot    | • Provide feedback to instructional designer | Content experts |                                                   |
| 11. Finalize all pilot materials and Prepare Facilitators | | Instructional designer  
Session 1: 8/26  
Session 2: 9/23 |                                                   |
| 12. Run pilot                             | | |                                                   |
| 13. Final revision following pilot         | Based on participant and facilitator feedback, make revisions to final course | Instructional designer |                                                   |
| 14. Configure course for Investigators     | Revise course for shorter version for investigators (e.g., less in-person practice) | Instructional designer  
Content experts |                                                   |
| Stakeholder review of investigator course  | | |                                                   |
Clinical Research Study Checklist Fairview Behavioral Health Services (Version 2016.04.26)

The purpose of this Checklist is to provide a process so that leadership and clinical staff can provide input into how clinical research is developed and performed on Fairview Behavioral Health Services and provide a mechanism for monitoring the status and progress of research projects. The Behavioral Health Services Research Oversight Committee will meet every 6 months to review the implementation of this checklist/process plan.

Directions:
- It is the responsibility of the primary investigator to initiate and complete this checklist
- The Executive Dyad will review and sign the checklist as endorsed or returned with feedback pre-IRB
- In the event the checklist is returned with feedback, the checklist may be re instituted once issues are addressed and the Dyad has endorsed by signature.

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Project Title</th>
</tr>
</thead>
</table>

1. Protocol Review and Gatekeeping
   a. Pre•IRB
      i. Investigator presents research plan to monthly clinical hospitalist meeting with key leadership present (unit medical directors, dyad leadership •• Knight and Banik) to discuss and get input on clinical research process. Decide if input is needed from the public or other stakeholders (e.g. patient family advisory board, NAMI, risk management). **Date Completed**
      ii. Implementation input from involved clinical unit. **Date Completed**
         1. Explanation of research purpose, plan and significance by investigator
         2. Primarily focused on the recruitment process, consenting/assenting process, procedures and roles of the staff.
         3. Define staff education needs.
         4. Assess/inquire with staff if there would be any additional clinical burden/delay in routine pt care that may occur with research implementation.
         5. Define communication needs. Document the input provided and each contributor.
      iii. Investigator finalizes research implementation plan based on input from unit staff. **Date Completed**
      iv. Dyad leadership (Executive Medical Director and Behavioral Health Administrator) reviews and endorses or returns with feedback pre•IRB implementation plan

   Endorsed: Signatures/Date  
   Returned with Feedback: Signatures/Date

   b. Post•IRB
      i. Investigator returns to the involved clinical unit meeting to update on IRB status, review any changes suggested by IRB if any, update research implementation plan as needed. **Date Completed**
      ii. Dyad leadership reviews and endorses post•IRB implementation plan. **Date Completed**
      iii. Dissemination to all unit staff:
         1. Investigator visits the Council and explains study. **Date Completed**
         2. Provide a 1-page study synopsis to support staff/physicians to reference. **Date Completed**
         3. Summary is sent by email to all using read•receipt mechanism. **Date Completed**

2. Research Monitoring
   a. Research begins. **Date Begun**
   b. Quarterly research updates by investigator to Unit Council and System Dyad Leadership. *(At this time, the clinical staff can also provide feedback and suggestions on how the study is going from a clinical staff perspective. Recommend updates to the protocol as indicated based on this discussion.)*
      **Dates Completed:**
   c. Between routine quarterly updates, if a concern about a study should arise, unit staff will approach the program director, who will raise the issue with medical director, dyad leadership, and/or investigators. **Dates Completed as applicable:**
   d. Feedback • On completion of the research project a presentation will be made to unit staff to inform of the results of the research. **Date Completed:**
Memo

To: Brooks Jackson
From: Mark Paller
Date: 6/30/2016
Re: status of research by Dr. Stephen Olson

In the last two weeks there have been numerous questions regarding the status of Dr. Stephen Olson, a faculty member in the Department of Psychiatry, with regards to his eligibility to participate in clinical research. I take this opportunity to provide you with a status report.

Presently, Dr. Olson is not participating in clinical research, a choice he made because of the harsh attention that has been focused on research he performed a decade ago. However, should he wish to re-engage in clinical research he must meet the following criteria that were outlined in the Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program Work Plan.

Enhanced Research Training and Oversight of Two Investigators in Department of Psychiatry

The External Review recommended that because of ongoing concern and criticism, two investigators in the Department of Psychiatry specifically should receive supervision, coaching in leadership, and advanced training in human participant protections. Part of this will be dealt with by the methods described in section 13. In addition, these investigators will be required to review all of the publications and associated sets of information cited previously in the references of section 9. More enhanced post-approval review will be undertaken (on a bimonthly basis) to make sure that all clinical research protocols that these investigators participate in are proceeding appropriately. The OVPR is planning a national symposium on human research participant ethics and these two investigators will be required to participate in this activity. Finally, a plan for leadership coaching of the two investigators will be developed and overseen by the Dean of the Medical School.

Dr. Olson is aware of these requirements and agrees to this plan should he wish to restart his research. He has been an eager and willing participant in all departmental discussions with regards to improving human research protections, specifically with regards to insuring better interactions with clinical staff before a clinical trial is begun and while it is being conducted, how to determine ability to provide consent, and how to avoid conflicts of interest when one is an investigator and the physician for a patient who might participate in one’s trial. Dr. Olson did attend the national symposium on human research participant ethics that was held on 2 December 2015. The entire department, including Dr. Olson, is awaiting finalization of other aspects of the Implementation Plan, including additional training, new policies, and CTSI oversight of psychiatric clinical research.
April 25, 2016

Mark S. Paller, MD, MS
Senior Associate Dean
Interim Head, Department of Psychiatry

Dear Dr. Paller:

During the faculty meeting of April 20, 2016, we discussed and approved the following Department of Psychiatry Dual Role Consenting Policy.

“To mitigate issues of therapeutic misconception when a study investigator is also the treating clinician of a potential study participant, the investigator/clinician should not be involved in the consenting process. Questions about the study should be answered by another study team member not involved in the potential participant’s clinical care. Potential participants should be given the option to see another clinician, not involved with the study to discuss treatment options before deciding to participate in the study.”

Sincerely,

Kelvin O. Lim, M.D.
Drs. T.J. and Ella M. Arneson Land Grant Chair in Human Behavior
Professor and Vice Chair for Research