Certification of IRB Approval

IRB Protocol Number: HS10-677
Title: Developmental Research Courses
Investigator(s): Sharon Carver
Department(s): Psychology
Date: January 4, 2011

Carnegie Mellon University Institutional Review Board (IRB) reviewed the renewal above referenced research protocol in accordance with the requirements of Public Law 99-158 as implemented by 45 CFR 46 and CMU’s Federalwide Assurance. The research protocol has been given APPROVAL by Expedited Review on January 4, 2011 as authorized by 45 CFR 46.110 (7) and 21 CFR 56.110. This APPROVAL expires on January 6, 2012, unless suspended or terminated earlier by action of the IRB.

All untoward or adverse events occurring in the course of the protocol must be reported to the IRB within three (3) working days. Any additional modifications to this research protocol or advertising materials pertaining to the study must be submitted for review and granted IRB approval prior to implementation. Please refer to the above-referenced protocol number in all correspondence.

Federal regulations require that all records relating to this research protocol be maintained for at least three (3) years after completion of the research, and be accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner.

The Investigator(s) listed above in conducting this protocol agree(s) to follow the recommendations of the IRB and the Office of the Provost of any conditions to or changes in procedure subsequent to this review. In undertaking the execution of the protocol, the investigator(s) further agree(s) to abide by all CMU research policies including, but not limited to the policies on responsible conduct research and conflict of interest.

The IRB maintains ongoing review of all projects involving humans or human materials, and at continuing intervals, projects will require update until completion. At the end of the current approval, a progress report and current consent form must be submitted to the IRB summarizing progress on the protocol during that period. Please be advised that the progress report requests information pertaining to women and minorities; therefore, this information should be tracked with your participants’ data.

Please call the Research Regulatory Compliance Office at 412-268-1901 if you have any questions regarding this certification. Thank you.

David Danks, Ph.D., Chair, IRB
Dear Parents,

The purpose of this letter is to describe the various Carnegie Mellon programs in which the Children's School is engaged and to obtain your formal permission to allow your child to participate in them. The Psychology Department's involvement in the Children's School includes -- in addition to financial support -- teacher preparation training and research.

Teacher Preparation Programs
In the general preparation program, teacher-trainees (undergraduates from Carnegie Mellon, Chatham College, and Duquesne University, etc.) learn all phases of preschool teaching and management. They work in the school with the children, assisting regular teachers in a variety of ways. Sometimes they design and carry out special projects - such as a math or science lesson - with the children. These projects are planned with Dr. Carver and supervised by the teaching staff.

A second type of teacher preparation program involves students who are training in areas other than preschool education, such as art or music. Students in these areas sometimes have special projects involving the preschool children. In one such project, an art teacher-trainee presented a light show for the children and instructed the children in every step of the show-construction process. These projects are supervised not only by the preschool staff, but also by faculty from the cooperating departments.

Programs for Psychology Majors
Advanced psychology majors with a special interest in children may take a course called Research Methods in Child Development. As part of this course, students learn observational methodology and practice observing and recording the behavior of the preschool children. Sometimes this is done from the main preschool observation booth; at other times, a few children are asked to come to a small playroom adjacent to the classrooms. In another part of this course, students learn to interact with a child in a testing or experimental situation. They practice administering a test and then may have the child participate in a learning or problem-solving situation of some sort. The purpose, of course, is to train the student, not to obtain information about the child. Any test scores obtained under such conditions are not considered valid and are not recorded anywhere in the child's records. Indeed, the students are not even given the last names of the children.

In all such course work, the students are continually supervised by psychology faculty. In addition, all course projects are discussed with Dr. Carver and have the full cooperation of the teaching staff.

Psychology Research
Several times during the year, the children may participate in research being conducted by members of the Psychology Department. In one recent project, for example, the five year olds looked at a series of slides and told the experimenter whether or not one picture "belonged" with another - where a letter "belonged" with a postman, a diamond ring "belonged" with a pigeon,
etc. They explained their reasons, and the experimenter was thus able to construct a theory of how young children differ from adults in their concepts of real world relations.

The ethical, legal and scientific issues surrounding the use of human subjects in psychological research are very complex, particularly when the subjects are children. These issues have received much attention in recent years from professional societies such as the American Psychological Association, the World Medical Association and The Society for Research in Child Development, and from Federal agencies such as the Department of Health, Education and Welfare, or the National Science Foundation, which support much of the research in our Department.

All research activity involving the use of human subjects conducted on our campus must be reviewed and approved by a university committee called the Institutional Review Board (IRB). The IRB has determined that research activity at the Carnegie Mellon Children’s School is limited to experiments that pose no more than “minimal risk” (A risk is minimal where the probability or magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.), and that the research activity is conducted in accordance with federal regulations governing the protection of human subjects in research.

Subjects must be informed of the general nature of what they are to do, why they are to do it, and what will be done with the information obtained. They must be free to refuse to participate or to terminate participation without any penalty, overt or covert, physical or psychological. In the case of children, we must first obtain consent from the parents - to whom we can explain the purposes of the experiment - and then from the children - to whom we can indicate our desire to have them participate and their option to agree or disagree to do so.

The child's right to privacy must in no way be infringed by the research procedures. In all of our experiments, only the principal investigator and the research assistant have access to the list that connects individual names to experimental data. In all further work, the child's identity is concealed, and experimental records are maintained separately from all other school records. No information about the child's performance is ever revealed to other children, teachers, or parents, beyond the fact of participation itself.

In addition to the IRB approval and the written parental consent, further approval must come from Dr. Carver regarding the participation at any particular time of any specific child, depending upon the teacher's assessment of the appropriateness of the child's participation at that time. Finally, the children always are asked, in the presence of their teachers, if they want to participate on a particular day. With very few exceptions, children enjoy these "special games" and typically they eagerly volunteer to participate.

You may find all of this rather elaborate and formal, but we want you to be aware of the extensive consideration we have given these issues and of the great responsibility we feel in involving your child in our programs. In actual practice, psychological research in the Children's School turns out to be a lot of fun for both the children and the adults involved.
In a typical experimental session, the child and experimenter go to a small playroom within the Children’s School where the child is presented with some task and asked to "play a game". The experimenter usually records the child's responses on paper and with audio or video equipment. The child is watched carefully for signs of worry or boredom and is always free to refuse to participate. As you might imagine, however, the children have such a good time that such refusals are extremely rare. Indeed, participation is viewed by the children as one of the "goodies" in the Children's School.

Please sign the enclosed form to indicate your willingness to let your child participate and return it to the Children's School as soon as possible. If you would like further information about the experiments or the general procedures outlined here, please feel free to call me (412-268-3151) or Sharon Carver (412-268-2199).

Sincerely,

Michael F. Scheier, Ph.D.
Professor and Head, Department of Psychology
CARNEGIE MELLON CHILDREN’S SCHOOL

CONSENT FORM
PSYCHOLOGY RESEARCH

My child, ________________________________________________, has my permission to participate in the educational and research projects conducted by the faculty and students of the Carnegie Mellon Psychology Department during the 2011/2012 academic year.

I have read and understand the letter from Dr. Scheier describing the nature of the research activity at the Children’s School. I am aware that I may call Dr. Sharon Carver (412-268-2199) or Dr. Michael Scheier (412-268-3151) if I have any questions. I have been informed of the general nature of these projects, their operating procedures and their administration, and I am aware that Dr. Carver will provide additional detail via the monthly newsletter or special memo prior to the conduct of the studies. In the case of final course projects, when the research descriptions are not available in advance, I understand that the research descriptions that will be sent home with my child after participation in a specific study.

I understand that

(1) by signing this consent form in advance of the study design, I am relying on Dr. Carver's professional expertise in determining the appropriateness of the research activities,
(2) all studies conducted at the Children's School have been deemed by the Institutional Review Board as posing no more than “minimal risk” to my child,
(3) my child has the right to refuse participation or to terminate participation in any specific study at any time without penalty,
(4) my child may be audio or video-taped during classroom activities or research sessions,
(5) no specific data about my child will be released to me or to the school personnel, and
(6) my child’s anonymity will be maintained in all analyses and presentations of research data, including audio and videotapes, by using participant numbers rather than names.

I have been provided with an additional copy of this consent form for my records. I am aware that I may direct questions about Carnegie Mellon’s research procedures to the Regulatory Compliance Administration, IRB Chair (412-268-4727).

__________________________________   ___________________
(Signature of Parent or Legal Guardian) (Date)
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