iStar ID: CCI-07-00057 (Modified) Application Version Date:5/13/2008
Version:2.5

Date: Wed May 28 17:06:32 2008 Print Close

1. Project Identification Information

1.1. * **Type of Submission**:

- (•) Research Protocol/Study/Class Project Only
- ( ) Grant/Contract Only
- ( ) Facilitated Review (CIRB)

1.2. **Full Title of Research Protocol**
Personalized Socially Assistive Human-Robot Interaction: Applications to Autism Spectrum Disorder

1.3. * **Short Title**
Soc. Asst. HRI - App. to ASD

1.3.1. **If there is a sponsor protocol number associated with this file, specify it here:**

1.4. * **Please indicate which IRBs you are requesting review from (check all that apply):**

- [ ] USC - Health Sciences IRB (HSIRB)
- [x] USC - University Park IRB (UPIRB)
- [x] CHLA - Committee on Clinical Investigations (CCI)

1.4.1. **If there are any individual collaborators from other institutions, check here:** [ ]

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2. Study Personnel (for a study already submitted to the IRB)

This screen indicates the active study team once the proposal has been submitted. This screen is not required during presubmission and should be left blank.

2.1. * **Principal Investigator (PI):**
Clara Lajonchere HS Certification: Current (7/28/2009)

2.2. **Study Coordinator or Contact Person:**
David Feil-Seifer HS Certification: Current (11/22/2008)

2.3. **Co-Investigators:**

Last	First	Organization	HS Certification	Expiration
Mataric	Maja	COMPUTER SCIENCE	Current	7/15/2010
Narayanan	Shrikanth	ELECTRICAL ENGINEERING	Current	7/23/2010

2.4. Other Study Personnel and their roles:

	Last Name	First Name	Organization	Study Role	HS Certification	Expiration	Obtain Consent
[View]	Wade	Eric	COMPUTER SCIENCE	Research Assistant	Current	9/12/2010	no
[View]	Williams	Marian	GENERAL PEDIATRICS	Clinical Consultant	Current	5/9/2011	no

2.5. * Is the Principal Investigator a student, resident, trainee, or visiting scholar?

○ Yes ◉ **No**

2.6. If yes, please designate a Faculty Advisor:

HS Certification: ()

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3. Required Department Approvals (for a study already submitted to the IRB)

This screen indicates the division/department approvals received once the proposal has been submitted. This screen is not required during presubmission and should be left blank.

3.1. Pending Division/Department Approvals:

Name Division/Department Parent Campus

There are no items to display

3.2. Received Division/Department Approvals:

Name	Division/Department	Parent Campus
RESEARCH ON CHILDREN, YOUTH AND FAMILY	Division	Childrens Hospital Los Angeles (CHLA)
PEDIATRICS	Department	Childrens Hospital Los Angeles (CHLA)

3a.3. (HSC Only) Other Health Science campus committees that will need to review and approve this protocol:

Committee Name Committee Chair Approval Memo

There are no items to display

3a.4. (HSC Only) Will the research be conducted through the GCRC?

○ Yes ◉ **No**

3c.3. (CHLA Only) Other CHLA hospital committees that will need to review and approve this protocol:

Committee Name Committee Chair Approval Memo

There are no items to display

3c.4. (CHLA Only) Are you planning to submit this study to the GCRC for review?

○ Yes ◉ **No**

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4. Type of Study Review

4.1. Please indicate the type of review that you are requesting for this study:
Expedited Review

4.2. Attach the Protocol, Sponsors template IC, Dissertation. For small investigator initiated simple studies an investigator developed protocol may not be necessary; however for larger, randomized, complex studies, multi-site studies a fully developed protocol may be needed. If you have questions contact the IRB office to discuss.

name	Version	Modified
ExperimentDesign.doc	0.03	5/30/2007 4:18 PM

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4a. Type of Study Review - Expedited Review

This screen is required if you are requesting an expedited review for this study (Question 4.1.)

4.1. Please indicate the type of review that you are requesting for this study:
Expedited Review

4a. If you checked expedited review, please choose the applicable category from the list and attach your data collection forms below (click on the abbreviated category to receive the full description):

	Short Description (click for full desciption)
☐	(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met...
☐	(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture...
☐	(3) Prospective collection of biological specimens for research purposes by noninvasive means...
☐	(4) Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves...
☐	(5) Research involving materials that have been collected, or will be collected solely for nonresearch purposes...
☑	(6) Collection of data from voice, video, digital, or image recordings made for research purposes.
☑	(7) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies...

4a.1. If you checked expedited review, please attach a copy of the forms you will be using to collect data, if applicable:

name	Version	Modified
There are no items to display		

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5. Study Location(s)

5.1. Indicate the locations where this study will be conducted by the USC/CHLA investigator(s) (check all that apply):

	Location
☐	HSC - Health Sciences Associated Locations
☑	UPC - University Park Associated Locations
☑	CHLA
☐	Other Sites/Institutions (In the US)
☐	Other Sites/Institutions (Outside the US)

5.2. (HSC or CHLA only) Is this a multi-site study?

○ Yes ◉ **No**

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6b. UPC Location(s)

This screen is required if you indicated UPC - University Park Associated Locations (Question 5.1.)

6b.1. UPC Locations (check all that apply and provide room numbers or location where indicated):

Location
☐ Faculty office
☐ Campus location
☑ Off-campus location

6b.2. If campus location, please specify:

6b.3. If off-campus location, please specify:
Childrens Hospital Los Angeles, 4650 Sunset Boulevard, Los Angeles, CA

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8. Funding Information

8.1. Are you or the institution receiving any financial support for the conduct of this study?

◉ **Yes** ○ No

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8a. Funding Information - Details

This screen is required if you indicated you or the institution are receiving financial support for this study (Question 8.1.)

8.2. If the funding source has undergone separate review by the IRB (i.e., cooperative group grants, umbrella grants, multi-project/program grants, center grants), please try to select it from the list using the "Add" button. If the funding source is not displayed in the list, enter the information in question 8.3.

Grant #	Principal Investigator	Grant Title

There are no items to display

8.2.1. If the grants selected in question 8.2 fund multiple studies, please attach the specific pages of the grant that are relevant to THIS study.

name	Version	Modified

There are no items to display

8.3. Please specify any funding source that is not listed in question 8.2. You will need to use the "Add" button for each funding source for this study.

	Sponsor	Principal Investigator	Type of Funding
[View]	Nancy Laurie Marks Foundation	Maja Mataric'	Foundation

8.4. (HSC ONLY) Consistency Checklist (HRA will upload):

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9. Methods and Procedures - Selected Descriptors

Note: The items listed below ARE NOT an all inclusive list of methods and procedures available to investigators. The list only includes items that will trigger additional questions specific to areas of research or are necessary for the review process.

9.1. * Social-Behavioral Procedures (check any or all that apply):

Specific Descriptor	
Behavioral Observations and/or Behavioral Experimentation	☑
Behavioral Interventions	☐
Deception	☐
Interview/Focus Groups	☐
Population-based Field Study	☐
Psychophysiological Testing	☐
Surveys/Questionnaires/Psychometric Testing	☐
Other Social-Behavioral Procedures	☐
None of the above Social-Behavioral Procedures apply to this study.	☐

9.2. * Medical Procedures/Considerations (check any or all that apply):

Specific Descriptor	
Biohazardous Substances	☐
Controlled Substances	☐
Emergency Treatment	☐
Gene Transfer Study	☐
Stem Cell Research	☐
Magnetic Resonance Imaging (MRI)	☐
Investigational/Approved Drugs and Biologics	☐
Investigational/Approved Devices	☐
Radiation exposure other than clinically indicated tests and/or therapy	☐
Radionuclides	☐
Substance Abuse Treatment (with medication)	☐
Surgery	☐
Venipuncture	☐
Other Medical Procedures/Considerations	☐
None of the above Medical Procedures/Considerations apply to this study.	☑

9.3. * **Data Collection Types (check any or all that apply):**

Specific Descriptor
☐ Banking of Specimens/Data (Creation of a repository)
☐ Prospective Collection of Specimens/Data
☐ Genetic Specimens
☑ Audio/Video Recordings or Photographs
☐ None of the above Data Collection Types apply to this study.

9.4. * **Does this study involve the use of existing/retrospective data/specimens?**

○ Yes ◉ **No**

9.5 * **Is this project an investigator initiated drug, biologic or device study?**

○ Yes ◉ **No**

9.6

(HSC and UPC ONLY) If the investigator is considered a sponsor/investigator for FDA regulated research he or she must complete and attach a USC Sponsor/Investigator Agreement. This must be completed and signed by the Sponsor/Investigator.

Name

There are no items to display

10. Characteristics of the Study Subject Population

10.1. **What is the maximum number of subjects you plan to recruit for this site? (Integer values only)**

65

10.1.1. **If this is a multi-site study, indicate the projected total subject accrual. (Integer values only)**

10.1.2. **Please provide further explanation of accrual goals, if necessary.**

10.2. **Indicate the inclusion criteria for enrollment. (HSC: *refer to specific sections of the protocol/grant, if applicable*)**

Participants with Autism Spectrum Disorder (ASD) will be studied; they will be selected with the assistance of the Autism Genetic Resource Exchange (AGRE) program at the Autism Speaks foundation. AGRE maintains a registry of pre-evaluated and categorized subjects for participant selection in research. Since many of our experiments do not explicitly require verbal interaction, we intend to invite participation from across the spectrum of ASD verbal abilities (ADOS modules 1 through 4).

One parent of the participant will participate in the study. This parent will interact with the robot and the child and be identifiable on the video recordings.

10.2.a. **If needed, copy-and-paste any tables here and reference in the question above.**
Tables

10.3. **Indicate the exclusion criteria for enrollment. (HSC: *refer to specific sections of the protocol/grant, if applicable*)**

The only exclusions are children not between 5 and 10 years of age and those who object to interacting with robots.

10.3.a. **If needed, copy-and-paste any tables here and reference in the question above.**
Tables

10.3.1. If there are any age, ethnic, language, or gender-based exclusion criteria, please provide justification.
We are interested in studying the social effects of human-robot interaction with people with ASD. In particular, we are interested in how this affects the development of socialization skills in children. Therefore, we wish to draw our sample from children between 5 and 10 in order to observe them at many points along the social development time line. Also, since none of the study personnel are proficient in languages other than English, study participants must be able to speak and understand English.

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11. Study Summary

11.1. Abstract: The abstract should be written in lay language and should have 1 or 2 sentences written to address each of the following points: background and rationale; objectives or purpose; study methodology; description of study arms (if appropriate); sample characteristics; study endpoints or outcomes; intervention and follow-up; statistics and plans for analysis.
We plan to observe the behavior of children with autism and compare their interaction with people to their interaction with robots. The child, robot, and a familiar person (a parent) will be together in an observation area. In some experiments, multiple versions of the robot or computer will be present in the room if the child is to select a preferred object for interaction. In some experiments, an unfamiliar person will also be in the room. Each child will participate in multiple sessions under different experimental conditions. Each session will last up to 1.5 hours (plus the time for a consent interview) and consist of shorter segments involving different experimental conditions and breaks.

In order to isolate the possibility that the child initially may be shy or otherwise not used to the observation setting, we will conduct a baseline segment at the beginning of the session and the end of the session. In the baseline, the child will be observed interacting without a robot present in the scene. We will place a neutral toy (one that does not move of its own accord) in the room as a focus for interaction.

11.2. Research objectives and background

11.2.1. Describe the specific objectives or aims of the study and hypotheses or research questions. (HSC: *refer to specific sections of the protocol/grant, if applicable*)
Objectives:

1. Examine the changes in social behavior of a child with Autism Spectrum Disorder (ASD) with robot as a social partner vs. a computer or another (unfamiliar) person.
2. Compare the interaction between the ASD child and the robot when the robot acts randomly vs. when the robot acts contingently relative to the child's behavior.
3. Compare responses to embodied robots to response to computer interfaces.
4. Compare responses to anthropomorphic robots (i.e., robots with human-like torsos with two arms and a head) to responses to non-biomimetic robots (i.e., robots with no animal-like appearance characteristics, i.e., no head, arms, legs, etc.).
5. Collect data to be used to develop speech, activity, and user state models for later use in human-robot interaction with ASD children.

Hypotheses:

• H1: The participant will engage in more social interactions with the physical robot (non-biomimetic or anthropomorphic) than with the simulated agent.
• H2: The participant's social interactions will be richer with the physical robot (non-biomimetic or anthropomorphic) than with the simulated agent.
• H3: Some participants will prefer biomimetic and anthropomorphic robots to non-biomimetic ones; correlation with level of function/deficit will be explored.
• H4: Simple imitation and turn taking with a robot can improve social interaction skills. A robot will be more successful as an object of shared attention in both direct and mediated interaction compared to a virtual computer agent as determined by increased eye gaze, shared attention, more initiative, and social routines.
• H5: A phased, developmentally-informed approach can lead to measurable improvements in communication form and function. Progressively moving from more predictable to unpredictable robot behavior will help keep engagement of the child while providing increasing set of interaction skill levels such as in terms of staying longer on topic.
• H6: Repeated, deliberate interactions with the robot over long periods of time will increase proactive social interactions.
• H7: Realistic social interaction scenarios tailored to the specific individual can improve the affect response behavior of ASD individuals.
• H8: Progressive introduction of appearance and behavior from non-biomimetic to increasingly anthropomorphic will lead to increased levels in function and form of social interaction skills.

11.2.2. Provide a summary of the background of the study, and explain how this research will contribute to existing knowledge. Describe previous work that provides a basis to show that the proposed research can be carried out without undue risk to human subjects. Include relevant citations. (HSC: *refer to specific sections of the protocol/grant, if applicable*)

There is growing evidence supporting that children with ASD respond better, socially and intellectually, to computers and robots than to humans in similar contexts. It also has been observed that robots can inspire social behavior in children with ASD. This work endeavors to develop a methodology for designing socially assistive robot systems that encourage, through social interaction, a measurable increase in social behavior as well as test implemented robot systems that address the hypotheses above. Major hurdles in this process includes constructing a robot system that can recognize, understand, and correctly act upon behavior observed in its user, especially one with special needs. To that end, we will collect data for constructing better models of behavior for children with ASD.

These experiments will contribute a greater understanding about how robots can be used to affect human behavior. By focusing on children with autism, we hope to begin the process of designing a robot for the purposes of socialization therapy. This will involve gathering data on movement patterns, vocal utterances, word and sentence patterns, and physiological data for the purposes of creating models of the specific patterns of children with autism.

Previously, this lab has conducted numerous experiments that used the robot in a therapeutic capacity. In each of these experiments [1,2,3], the robot was used safely and without incident or injury. In these experiments, the robot exhibited similar, if not exact, behavior to what we are planning for this experiment. Other work [6,7] has used a therapeutic robot with non-patient subjects. Previous work has been conducted with children with autism and robots [4,5]. In these experiments, children with autism have interacted with robots for therapeutic and diagnostic investigations. In both cases, the interactions were conducted safely and effectively.

[1] Rachel Gockley and Maja J. Mataric´. "Encouraging Physical Therapy Compliance with a Hands-Off Mobile Robot". In 1st Annual Conference on Human-Robot Interaction, pages 150-155, Salt Lake City, UT, Mar 2006

[2] Maja J. Mataric´, Jon Eriksson, David J. Feil-Seifer, and Carolee J. Winstein. "Socially Assistive Robotics for Post-Stroke Rehabilitation". In Journal of NeuroEngineering and Rehabilitation, 4(5), Feb 2007

[3] Kyong Il Kang, Sanford Freedman, Maja J. Mataric´, Mark J. Cunningham, and Becky Lopez. "A Hands-Off Physical Therapy Assistance Robot for Cardiac Patients". In Proceedings International Conference on Rehabilitation Robotics, pages 337-340, Chicago, Illinois, Jun 2005

[4] K. Dautenhahn and I. Werry and J. Rae and P. Dickerson and P. Stribling and B. Ogden. Robotic Playmates: Analysing Interactive Competencies of Children with Autism Playing with a Mobile Robot. Socially Intelligent Agents: Creating Relationships with Computers and Robots. Kluwer Academic Publishers. 2002.

[5] B. Scassellati. Using social robots to study abnormal social development. Proceedings of the Fifth International Workshop on Epigenetic Robotics: Modeling Cognitive Development in Robotic Systems. Nara, Japan. Jul. 2005.

[6] Adriana Tapus and Maja J. Mataric´. "User Personality Matching with Hands-Off Robot for Post-Stroke Rehabilitation Therapy". In Proceedings, International Symposium on Experimental Robotics (ISER), Rio de Janeiro, Brazil, Jul 2006.

[7] Adriana Tapus, Cristian Tapus, and Maja J. Mataric´. "Hands-Off Therapist Robot Behavior Adaptation to User Personality for Post-Stroke Rehabilitation Therapy". In IEEE International Conference on Robotics and Automation (ICRA), Rome, Italy, Apr 2007.

12. Methods and Procedures - Prospective Studies

12.1. Describe in detail the design and methodology of the study. If applicable, include information on stratification or randomization plans. Identify and distinguish between those procedures that are standard of care and those that are experimental. Include the frequency and duration of each activity and the total length of subject participation. (HSC: *refer to specific sections of the protocol/grant, if applicable*)

We aim to validate our HRI model on a robot system designed for use with both typical children and ASD children of varying diagnosis. Toward that end, the experiments will be designed around the following social interaction-centered scenarios:

(1) The robot and the child will interact together by maintaining suitable personal space. When the child moves too close to the robot, the robot will back away. When the child moves too far away from the robot, the robot will move closer to the child. When the robot is not facing the child, it will turn to face the child. This condition will be compared to one where the robot moves randomly, not in response to the child's movements.

We will also compare a robot with a humanoid torso on top to one without a torso in each condition. Target of study: contingent-based behavior, comparison of anthropomorphic robot to non-biomimetic robot.

(2) The robot will use the arms on a humanoid torso to imitate the movements of the child. This condition will also be compared to one where a computer-generated agent (similar in morphology to the robot) is used instead of the robot. Target of study: contingent-based interaction, embodied robots compared to computer interfaces.

(3) The robot will use its embodiment to perform exaggerated and repetitive demonstrations of social gestures in an attempt to guide the user to imitate. The child will sit or stand freely near the robot as above,sufficiently far to be able to imitate the physical expressions of the robot (displayed in its face, torso, and gross body, depending on the embodiment). Target of study: semistructured interaction through imitation.

(4) The robot will use a small device to blow bubbles. The bubbles will either be at random intervals, or in response to prompts from the child. Target of study: non-verbal interaction and initiation of behavior.

Each of the above scenarios is an experimental form of care lasting up to 1.5 hours (including consent interview and questions); participants may return for repeated sessions, but repeated sessions are not expected or required. For the scenarios above that have multiple conditions, the order of conditions will be randomized. The time-extended interaction will provide the opportunity to test how assistive HRI can provide repetition, verbal integration of visual and motor/movement stimuli, and rehearsal as part of the behavior protocol, so as to help the child create a narrative reconstruction of a social scene that can be used as a basic skill for interactive social therapy. This is a fundamental component of our HRI design, based on the observed narrative impairment in children with ASD who become preoccupied in ritualized motor behaviors in order to “re-play” a sentence again and again to recognize patterns between objects in the world.

In each of these situations, a parent will be asked to be in the room. The role of the parent is to be a second social partner in the room, but with no explicit agenda or instructions.

Our prior work has already demonstrated the robot’s ability to safely follow the user around and engage the user through speech and movement. Such open-ended interaction will be employed, allowing the child to move about and be as un-constrained as is practically possible within the constraints of the data collection system. For safety and familiarity reasons, a PhD student will observe from outside the experimental area and a family member of the participant will sometimes be present in the experimental area as a second social partner in the room, but with no explicit agenda or instructions. The former will not actively interact with the participant during the experiments; the latter will participate under certain experimental conditions.

The participants will be monitored using video cameras (one overhead, one mounted on the robot, and stationary video-cameras), a physiologic data sensor mounted on an armband, and a microphone that the participant will wear. In addition, the robot will keep a text log of its observations and its actions. All data will be stored on a secured hard drive, indexed by randomly assigned participant number.

12.1.a. If needed, copy-and-paste any tables here and reference in the question above.
Tables

12.2. Provide a detailed description of the planned data collection, specific outcomes, and criteria for evaluation and endpoint definition. (HSC: *refer to specific sections of the protocol/grant, if applicable*)
Multi-modal data will be collected from all trials. We will be recording the scene using two standard video camera recorders. These will be placed so that one can observe the child's face, and the other can survey the people in the scene and the robot. In addition to standard video cameras, we will use a wide-angle lens (fish-eye) overhead camera mounted on the ceiling. We will also use a microphone mounted on the robot to record speech data. Finally, we will use a physiologic data sensor where possible. See attached file for details.

12.2.a. If needed, copy-and-paste any tables here and reference in the question above.
Tables

12.3. Describe the statistical considerations for the study, how the sample size was determined, and how the results will be analyzed, if applicable. (HSC: *refer to specific sections of the protocol/grant, if applicable*)
Analysis will be conducted by watching the video-coding data and conducting micro-behavior analysis of social behavior shown in the video as well as pattern analysis to look for coincident behavior that occurs during a session. The quantitative measurements will be used to show any increase or decrease in social behavior. The pattern analysis for coincident behavior can be used for a qualitative analysis to show the richness of the social behavior.

We will use this analysis as a quantitative measure of social behavior that occurs in each segment. We will use the baseline segments as a measure of "naturally occurring" behavior. We will compare this baseline to the segments including a robot to evaluate the effects of the presence of a robot. We will compare the two other segment types to evaluate the effectiveness of contingent behavior.

Sample size has not yet been definitively determined. The researchers will run a pilot consisting of 16 children. Using the preliminary data from that pilot, a principled sample size will be determined. We estimate

that 35-65 participants will be required, though that estimate is based on a very small sample size.

12.3.a. If needed, copy-and-paste any tables here and reference in the question above. Tables

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22. Special Subject Populations

22.1. Special Subject Populations (Check all that apply).

Population	
Normal Volunteers	☐
Employees	☐
Students	☐
Adults not Competent to Consent	☐
Non-English Speaking Populations	☐
Minors (subjects under 18 years of age)	☑
Pregnant Women, Human Fetuses, or Neonates	☐
Prisoners/Detainees	☐
Wards	☐
None of the above	☐

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22d. Special Subject Populations - Minors

This screen is required if you indicated Minors (subjects under 18 years of age) as a special subject population (Question 22.1.)

22d. If you selected Minors, answer the questions below.

22d.1. Provide a justification for involving minors in this research.
Since autism is a childhood onset disorder, our subjects will necessarily be children. Since the primary goal of the study is to observe autistic children and their interaction with robots and humans, the inclusion of this particularly vulnerable population is scientifically essential.

22d.2. Choose the proposed category of permissible research with children.

Category	
a. 46.404 - Research not involving greater than minimal risk.	◉
b. 46.405 - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual.	○
c. 46.406 - Research involving greater than minimal risk and no prospect of direct benefit to individual, but likely to yield generalizable knowledge about the subject's disorder or condition.	○
d. 46.407 - Research not otherwise approvable which presents an opportunity to understand, prevent or alleviate a serious problem affected the health or welfare of children.	○
None of the above categores; Minors will not participate in this study.	○

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23. Subject Identification and Study Resources

23.1. Describe the method(s) by which subjects will be identified, eligibility will be determined, and by whom.
Participants will be identified and eligible families will initially be contacted by AGRE through a study flyer that will be mailed to families. Interested families are instructed on the flyer to contact USC directly.

23.2. Describe the time the investigators have available to conduct and complete the research and justify that it is sufficient.
We have allotted 12 months for the pilot from the start date and 24 months for the full study from the start date.

23.3. Describe the staff and justify they are adequate in number and qualifications.
Maja Mataric, Ph.D

Shrikanth Narayanan, Ph.D - Professor of Electrical Engineering and Jointly in Computer Science, Linguistics and Psychology
Director, Speech Analysis & Interpretation Laboratory

Clara Lajonchere, Ph.D - Vice President of Clinical Programs
Autism Speaks
Adjunct Clinical Assistant Professor of Pediatrics
Keck School of Medicine

Dr. Eric Wade

Dr. Marian Williams -

23.4. Describe the study facilities and justify they are adequate.
The study team will utilize rooms at USC and at Children's Hospital Los Angeles. All of the repeated-measures studies will take place in a room equipped with an overhead camera and with eye-level observation cameras

23.5. Describe how the investigators will ensure that all persons assisting with the research are adequately informed about the protocol and their research–related duties and functions. Include a description of how research staff, research and clinic nurses, other participating physicians, pharmacists, data managers, coordinators and others will receive necessary information and training.

Study coordinator will be well-informed of the present study and will be working under the supervision of Dr. Maja Mataric, Dr. Shri Narayanan and Dr. Clara Lajonchere. Everyone working on the data for the study will be certified by CITI or CCI.

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24. Subject Recruitment

24.1. Recruitment Tools (Check all that apply):

	Tool
☑	E-mail
☑	Flyers
☐	Letters
☐	Newspaper/Magazine Advertisements
☐	Radio/Television Announcements
☑	Subject or Participant Pool
☑	Telephone Scripts

Tool
☑ Verbal (Personal Solicitation)
☐ Website
☐ Other
☐ None of the above

24.1.1. If Other Recruitment Tool, please specify:

24.2. Attach copies of all recruitment tools indicated above.

name	Version	Modified
Flyer.rtf	0.04	5/13/2008 2:56 PM
Robotics Recruitment Script.doc	0.01	5/1/2007 12:18 PM

24.3. Describe in detail all recruitment strategies for each participant group involved in this study. Explain how you will have access to a population that will allow recruitment of the required number of participants. Explain who will approach the participants, how and when the participants will be approached, and what will be said.
Flyers will be sent to eligible participants as determined by AGRE. Participants will be instructed to contact the USC Robotics Lab directly. Contact person for the study will be Study Coordinator, David Feil-Seifer (USC UPC)

24.4. What measures will be taken during the recruitment and consent process to safeguard against potential coercion or the appearance of coercion?
Although we will offer reimbursement for parking and a $25 gift card, there are no other payments offered for participation. In addition, families will be reminded during the recruitment and consenting processes that their participation is entirely voluntary and that they may drop out of the study or discontinue their participation at any time for any reason. During the informed consent process, we will go over the consent form in detail with the family, making sure that all of their questions have been answered and that they understand the voluntary nature of their participation.

25. Financial Obligation and Compensation

25.1. Financial Obligation: Describe any financial obligations that the subject may incur as a result of participating in the study. Indicate which costs will be covered by the study.
Participants in the study will be reimbursed for parking and travel expenses. No financial obligation will be required for participation.

25.2. Payment for Participation: Describe how much, if any, financial or other form of compensation will be provided to the subject/family. Describe the requisite conditions that must be fulfilled to receive full or partial compensation. Descibe the proposed method of timing and disbursement. If children are involved, please specifically address how the compensation will be distributed to children.
Subjects will be given Target gift cards worth $25.00 at the conclusion of their participation.

25.3. Emergency Care, Injury and Compensation for Injury: If participants were to require care, medical or psychological services as a consequence of the research, how will they be made available? If applicable, describe how the financial liability for research-related injuries would be handled.
The research presents only minimal risk to subjects. Therefore no research-related injuries are expected to result from subjects' participation.

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26. Data Privacy and Confidentiality

26.1. How will the data for this study be collected and recorded? Describe the provisions to protect the privacy of the individual. *(e.g. consenting/screening subjects in a private office or area versus a busy hospital waiting room). NOTE: See guidance link for definition of privacy and examples.*
Data will be collected and stored on videos. The videos will be used solely for research purposes and will not be shown to anyone without the prior consent of the participants. Video data will be stored on secured hard drives, file names will only refer to a non-identifying subject identification number.

Data from a physiologic data armband and audio data from a microphone will also be collected and stored on secured data storage. Files will only be referred to by subject ID number.

26.2. How will the data be recorded to protect personal privacy (select one)?
Coded (Data will be linked to subjects with a code)

26.2.1. If Other is selected, please specify.

26.3. Where will the research data be stored? Please specify the physical location and how it will be secured to protect confidentiality.
Recordings and information about subject's age and gender along with physiological data and robot interaction log will be kept in a locked office or in a locked cabinet in a locked laboratory on the USC campus. Only members of the research team will have access to these recordings.

26.4. Who, other than the specified study team, will have access to the study records or data? Specify their name, role and affiliation. Do not list study personnel already listed on screen 2.

	Name	Role	Affiliation
[View]	ThirdPath Creative Group (Adam Gordon and Stephen Epstein)	Video post-production	Outside Contractor

26.5. If coded or identified data will be released, specify the persons, agencies to whom the information will be released. Please also indicate the provisions that will be taken to assure that the transmission of the data will maintain confidentiality.
Coded data will be released to ThirdPath Creative Group, for video post-production. They will assemble a presentation video (including de-identifying the faces from the video). This video will be used to educate others about the experimental approach for a robot-assisted intervention for children with ASD represented by this research.

As, outlined in the consent form, images will be disguised (boxes will be placed over eyes), names will be replaced with codes, and any instances where the audio recording for the video captured a subjects name will be erased out. In order to accomplish these safeguards as well as to edit down the data/footage for an education video, the research team will employ an outside consultant for video post-production. The vendor will be responsible for assembling the video (including de-identifying the faces from the video and erasing any audio that references names). Prior to receiving the data/footage, the vendor will meet with the research team to discuss the issues surrounding human subjects research and will be required to sign a CHLA data agreement. The agreement specifies that:

1. Dr. Clara Lajonchere agrees to not release or disclose the key to the coded data/footage to Consultant.
2. Consultant agrees not to obtain the key to the code for the data/footage they are receiving.
3. Consultant agrees to put black boxes over the eyes of any people included in the video footage (i.e. parents and children).
4. Consultant agrees not to share this data/footage with any other researchers, colleagues, potential clients, and/or students who have not already been approved by Dr. Clara Lajonchere and the CHLA CCI.
5. Consultant agrees to store this data on a secure local drive on their computer and to not save it onto their local program/division's network drive.
6. Consultant agrees to delete all files relating to this data/footage, once the final and approved educational video has been delivered to Dr. Clara Lajonchere.
7. Consultant agrees not to use this data/footage for any self-promotion (e.g. not to be included in a portfolio, or on their company's website).

Videos will be hand-delivered by study coordinator David Feil-Seifer on DVD to ThirdPath's editing facility. Once delivered and uploaded on ThirdPath's computer, the DVD will be destroyed. All files stored on the DVD, or on the hard drive will only be identified by a participant ID number.

Once this agreement has been met, and CCI has approved this process. The data/footage which will be catalogues by code numbers only will be provided on a DVD. The code that links subject names to code numbers on the data/footage will never be supplied to the Consultant. Once the Consultant has completed the production of educational video, they will deliver all files to the research team and delete any data/footage from their system.

26.6. Describe what will happen to the data or data set, when the study is completed. Please indicate your plans for destruction of identifiers at the earliest opportunity consistent with the conduct of the research and/or clinical needs, if applicable.
Data will be stored on removable media (USB hard drives) and that media will be kept in a locked cabinet indefinitely. Since this data will be used for creating speech and behavior models of children with autism, the need for the data will last as long as research is done in this lab on children with autism. Therefore, the data will be kept as long as the PI remains at CHLA and is researching autism.

26.7. Will a Certificate of Confidentiality be obtained for this study?
○ Yes ◉ **No**

26.7.1. If yes, please attach the Certificate of Confidentiality if applicable.

26.8. If audio/video recordings or photographs will be used, specify your plans for deidentifying or anonymizing the material and when it will be destroyed.
Recordings made for the purposes of data collection will stored indefinitely. No provision to anonymize the data will be executed. If a subject decides to withdraw from the study either during or after experimental session, then at their request, recordings made of that subject will be deleted.

We will keep the data indefinitely in order to re-use the collected data for modeling work later. This work will involve using the collected audio, video, log, and physiological data in order to generate better-tuned models of behavior and physiological response for children with autism. Since we will be using video data containing faces and audio data that may contain names, we cannot anonymize the data either.

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27. Risk/Benefit Assessment - Risks

27.1. Risk classification for this study (select one).
Minimal Risk

27.2. Risks, Discomforts and Potential Harms: Describe the risks associated with each intervention. Include consideration of physical, psychological, social, and other factors. If data is available, estimate the probability that a given harm may occur and the potential reversibility. (HSC: *refer to specific sections of the protocol/grant, if applicable*)
Potential risks for subjects who consent to interaction with the robot are limited to injury resulting from physical contact with the robot. The robot is kept at low speeds, so injury would be minimal if any contact occurred. There are few exposed moving parts so a light bump is all that would be expected. In over 5 years of previous lab use, there have been no reported injuries as a result of robot collisions. In addition, there is a potential risk of accidental release of confidential information.

27.2.a. If needed, copy-and-paste any tables here and reference in the question above.
Tables

27.3. Describe the safety precautions that will be taken to minimize risks/harms. (HSC: *refer to specific sections of the protocol/grant, if applicable*)
The robot is equipped with both laser and sonar sensors to detect both where the child is and where obstacles to movement are located. The robot is programmed to stop when it is near an obstacle, and to back away when it is too close. In addition, the robots have E_STOP buttons which will immediately stop the robot's motors. These can be activated remotely via computer connection, or by pressing them directly on the robot. All study personnel will be trained on how to prevent collisions. See attached document for details about the robot.

To prevent the accidental release of participant data, data will be coded and kept in a secure, locked location.

27.3.a. If needed, copy-and-paste any tables here and reference in the question above.
Tables

27.4. Data Safety Monitoring Plan: Describe who will monitor the studies for the safety of the participants (investigators, sponsor, independent monitor, DSMB, etc). Provide a plan (Monitoring provisions) which may include information on: the type of data or events to be captured, who is responsible for monitoring data related to unanticipated problems and adverse events, time frames for reporting adverse events and unanticipated problems to the monitoring entity, the frequency of assessments of data / events captured by monitoring, specific triggers or stopping rules that dictate when an action is required, and procedures for communicating to the IRB, sponsor, investigator, and other appropriate

officials the outcome of the reviews by the monitoring entity.
Not applicable.

27.4.1. (CHLA Only) Attach the CHLA Research Monitoring Plan.

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28. Risk/Benefit Analysis - Potential Benefits and Alternatives

28.1. Describe any potential for direct benefits to participants in the study. There may be no direct benefits.
Children with autism may benefit from the interaction with the robot as a means of promoting social skill development.

28.2. Describe any potential benefits to society.
The results of this study will contribute to our knowledge of how autistic children interact with robots as we work towards designing robots as compelling social partners, catalysts for social interaction between children with autism and the general population and as tools in special education.

28.3. Alternatives to Participation: If applicable, describe alternatives (research or non-research) that are available to subjects if they choose not to participate in this study. This could include not participating in the study.
Subjects can choose whether to be in this study or not. If subjects volunteer to be in this study, they may withdraw at any time without consequences of any kind. Subjects may also refuse to answer any questions they do not want to answer and still remain in the study.

28.4. Risk/Benefit Analysis: This analysis should indicate if the risks to subjects are reasonable in relation to the benefits (if any) to the subjects and the benefit or importance of the knowledge expected to result.
Since this study involves minimal risk, the benefits that could emerge from this research appear to support a favorable risk/benefit ratio.

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29. Informed Consent and Waivers

29.1. * Indicate the types of consent that will be involved in this study (check all that apply):

	Consent Type
☑	Written/signed consent by the subject
☐	Written/signed consent by a legally authorized representative (for an adult)
☑	Written/signed permission for a minor by a parent or legal guardian
☑	Written/signed assent by a minor
☐	Verbal consent or written information sheet
☐	Consent will not be obtained for this study

29.1.1. Attach copies of all of the informed consent/assent, information sheet, and verbal script documents that will be used for this study

name	Version	Modified
Assent Form (14-17)	0.03	5/6/2008 3:31 PM
Assent Form (7-13)	0.04	5/13/2008 3:19 PM
Consent Form (Parent)	0.04	5/6/2008 3:38 PM

29.2. * **Waivers: If you are applying for any waivers of consent (check all that apply).**

Waiver Type	
Waiver of consent	☐
Waiver of assent	☐
Waiver of parental permission	☐
Waiver of written or signed consent (i.e., information sheets, telephone consent, verbal script)	☐
I am not applying for a waiver	☑

Note: Waivers of consent are not applicable if the research is subject to FDA regulations, except the following.

FDA Exception from general requirements:

1. **Waivers of Informed Consent in FDA-regulated studies are permissible in case of life-threatening situations, inability to communicate, not sufficient time and no alternative method, even if research presents more than minimal risk [21CFR50.23];**
2. **If the study satisfies the requirements under 21CFR50.24 "Exception from Informed Consent Requirements for Emergency Research."**

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30. Description of Informed Consent Process

30.1. Personnel Obtaining Consent: indicate the names and qualifications of study personnel who will be involved in the informed consent process.
Consent/assent will be obtained and documented by trained personnel from the Center for Robotics and Embedded Systems under the supervision of Dr. Lajonchere. Study coordinator David Feil-Seifer will handle all consents, and is well trained in the process of obtaining informed consent.

30.2. Describe the consent process. Discuss when and where the consent process will take place relative to the initiation of the study procedures, as well as, how opportunities will be made for possible participants/families to discuss their participation with others before signing the consent form. Describe the steps taken to provide the prospective participant sufficient opportunity to consider whether or not to participate in the study.
The process of obtaining consent will be conducted prior to the experimental testing. At this time, the participants and their family will have been provided information on the study and will have been contacted by telephone during which the study will have been explained in detail. The consent/assent will be reviewed section by section, allowing time for questions after each section. Consent will be done in a room at Children's Hospital adjacent to the room where the study will take place.

Currently, no specific room has been chosen for the consent interview. When that room is chosen, IRB committee will be informed.

30.3. Describe the steps that will be taken to assure that subjects (including children) fully understand the nature of their involvement in research.
Participants who are capable of giving written assent are asked to sign the Assent Statement. The assent process is conducted in the presence of a parent or legally authorized representative. It is stressed that participation is completely voluntary and that withdrawal at any time for any reason is permitted.

30.4. Will you be recruiting non-English speaking subjects?
○ Yes ◉ **No**

30.5. Describe how capacity for consent will be determined if some or all of the subjects have cognitive and/or language/hearing impairments.
The parent or legal guardian will be asked if participants have sufficient cognitive skills, reading ability and/or receptive language to undergo the assent process. Also, consenting person should be able to read at the 3rd grade level.

30.5.1. If applicable, attach any instruments that will be used to determine the subject's capacity to consent.

name	Version	Modified
There are no items to display		

30.6. Describe the procedures for identifying a legally authorized representative/guardian for those unable to consent (adults) or for minors not accompanied by their parents, as applicable.
N/A

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35. Is the HIPAA Privacy Rule Applicable?

35.1. Do you intend to access, use or disclose protected health information (PHI) in order to abstract medical record data (even if you are de-identifying the data abstracted), identify potential participants or to conduct your research?

◉ **Yes** ○ No

35.2. If Yes, do you intend to use data that contains any of the 18 elements defined by HIPAA as identifiers (listed below), in your research?

◉ **Yes** ○ No

The HIPAA Privacy Rule regulations [45 CFR 164.514(b)] lists 18 specific elements that are considered to be personal identifiers. The list includes:

- Name/Initials
- Street address, city*, county*, precinct*, zip code*, or equivalent geocodes*
- All elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death)*
- Elements of date, including year, for persons 90 or older
- Telephone number
- Fax number
- Electronic mail address
- Social Security Number
- Medical record number
- Health plan identification number
- Account number
- Certificate/license number
- Vehicle identifiers and serial numbers, including license plate number
- Device identifiers and serial number
- Web addresses (URLs); Internet IP addresses
- Biometric identifiers, including finger and voice print
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic or code

35.3. Are you only going to obtain data marked with an asterisk (*)? If so, you may be able to obtain or use such health information from a healthcare provider for research purposes without an authorization under the HIPAA privacy rules regarding "limited data sets". If applicable, attach a copy of the signed Data Use Agreement below.
There are no items to display

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36. HIPAA Analysis

This screen is only required if you indicated HIPAA is applicable by answering "yes" to Question 35.1.

36.1. If you are using or accessing protected health information in order to identify potential participants, indicate whether these activities fall under the rules for Activities Preparatory to Research or whether you will be applying for a Partial Waiver of HIPAA Authorization for the purposes of screening and recruiting.

- ○ (CHLA Only) Activities Preparatory to Research
- ○ Partial Waiver of HIPAA Authorization for screening, recruiting, and identifying subjects
- ◉ None of the Above

36.1.1. (CHLA only) If you have indicated that your access of clinical records (PHI) to identify subjects falls under the classification of Activities Preparatory to Research (36.1 above), please certify the statements below and ensure they are addressed in question 22.1. and sponsors protocol.

By checking the "I Agree" box you are providing assurance to the following:

- The use or disclosure is sought solely to review PHI as necessary to prepare the research protocol or other similar preparatory purposes;
- No PHI will be removed from the covered entity during the review; and
- The PHI that the researcher seeks to use or access is necessary for the research purposes.

☐ **I agree to all of the above.**

36.2. For study research, please indicate whether you will be obtaining authorization from the subject or requesting a Full Waiver of HIPAA Authorization.

◉ Obtaining HIPAA authorization from subject

○ Full Waiver of HIPAA Authorization

36.2.1. If you are obtaining authorization from the subject, attach the HIPAA authorization forms here (USC Only).

name	Version	Modified

There are no items to display

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39. Conflict of Interest Information

39.1. Do any of the participating study investigators or other research personnel (or their immediate family/significant other) have a financial and/or intellectual property interest in the sponsor or products used with this project? (See Guidance for CHLA Conflicts of Interest and Commitment in Research policy.)

○ Yes ◉ **No**

39.2. If yes, attach a completed Financial and Intellectual Interest Disclosure Form for each person who has a potential conflict to be managed. (download the form here)

name	Version	Modified

There are no items to display

39.3. To the investigator's knowledge does the Institution have financial and or intellectual property interests in the sponsor or the products used in this project?

○ Yes ◉ **No**

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40. Additional Supporting Documents

40.1. Attach any other documents that have not been specifically specified in previous questions, but are needed for IRB Review. For additional documentation that may be required for HSIRB Submissions, please consult the HSIRB Checklist.

name	Version	Modified
NSF-HRI Autism Submitted2006.pdf	0.01	4/30/2007 10:25 AM
Pictures of Robots.doc	0.01	3/13/2007 4:34 PM
ThirdPath Data Sharing Agreement	0.02	4/8/2008 11:11 AM
UPC IRB Approval Letter	0.01	6/18/2007 5:48 PM

40.2. If there is any additional information that you wish to communicate about the study please include it below. Please note, this section should not be used in lieu of or instead of the standard application items.

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99. Instructions for Study Submission

Congratulations! You have completed the application for a new protocol. When you are sure of the content, the following steps may be taken to submit your study for review.

For HSIRB Submissions, please consult the HSIRB Checklist found here.

For UPIRB Submissions, please consult the UPIRB Checklist found here.

1. Click the **"Finish"** button on the top or bottom application navigator bar to return to the study folderspace.
2. Use the SmartForm Progress Calculator to determine that all sections of the application are filled out correctly.
3. Use the **"Send Study Ready Notification"** activity to send an email to the Principal Investigator and Co-Investigator's with instructions for reviewing and submitting the application.
4. **All listed Co-Investigators (Question 2a.3, 2b.3, or 2c.3.) must use the "Agree to Participate" activity and answer yes.**
5. Once all the Co-Investigators have agreed to participate, the **Principal Investigator** (Question 2a.1, 2b.1, or 2c.1.) can submit the study by using the **"Submit Application to ____"**, where ____ indicates the IRB you are submitting to.
6. The PI will have to check the PI endorsement box. The PI will also have to check the student endorsement box if it is applicable.
7. The study is submitted. The state indicator in the top left of the study folderspace will no longer display Pre Submission.
8. The PI and Study Coordinator will receive an email confirming the application has been submitted.

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8.3. Funding Source

8.3.1. * **Name of Sponsor:**
Nancy Laurie Marks Foundation

8.3.2. * **Named Principal Investigator:**
Maja Mataric'

8.3.3. **Institution awarded the grant-award:**
University of Southern California

8.3.4. **Grant-award number provided by the Sponsor:**
NLMF/2008

8.3.5. **Title of the Funding Project, if applicable:**
Socially Assistive Robotics For Socialization and Communication Training of Children with Autism

8.3.5.1. If this funding project has been assigned an IRB number, please list it here:

8.3.6. * **Type of Funding:**
Foundation

8.3.6.1. If Other type of funding is selected, please specify:

8.3.7. Attach a copy of the proposal/contract/grant with the project budget. If this is a subcontract, also attach a copy of the institution's IRB approval:

name	Version	Modified
NLM Proposal	0.01	5/6/2008 3:13 PM

8.3.8.

(HSC ONLY) Please indicate where the funds will be deposited and the amount:	
☐ USC	Total:$0.00
☐ HRA	Total:$0.00
☐ Other, Specify:	Total:$0.00

26.4 Personnel with Access to Records at USC/CHLA

26.4.1. * Name:
ThirdPath Creative Group (Adam Gordon and Stephen Epstein)

26.4.2. * Role:
Video post-production

26.4.3. * Affiliation:
Outside Contractor