

**AWARD NUMBER:** W11XWH-16-1-0492

**TITLE:** Treating Gastrointestinal and Autism Symptoms in Adults with Autism Using Microbiota Transfer Therapy (MTT)

**PRINCIPAL INVESTIGATOR:** James B. Adams

**RECIPIENT:** Arizona State University

**REPORT DATE:** September 2020

**TYPE OF REPORT:** Annual Report

**PREPARED FOR:** U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

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<b>4. TITLE AND SUBTITLE</b> Treating Gastrointestinal and Autism Symptoms in Adults with  Autism Using Microbiota Transfer Therapy (MTT)			<b>5a. CONTRACT NUMBER</b> W81XWH-16-1-0492	
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			<b>5e. TASK NUMBER</b>	
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<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  ARIZONA STATE UNIVERSITY JANIE MORALES-CASTRO 660 S MILL AVE STE 312 TEMPE AZ 85281-3670			<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>  2020 Annual Report	
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<b>13. SUPPLEMENTARY NOTES</b>				
<b>14. ABSTRACT</b> Purpose: The purpose of this study is to determine the safety and efficacy of Microbiota Transfer Therapy for adults with autism and chronic gastrointestinal problems. Scope: The scope of the project is a randomized, double-blind, placebo-controlled trial of MTT for 84 adults with autism. The trial also includes an extension, partial cross-over, and long-term follow-up (6, 12, and 18 months). It includes extensive evaluation of autism-related and gastrointestinal symptoms, evaluation of microbiome composition, and blood safety tests. It includes 84 neurotypical controls (half with GI symptoms, half without) for comparison of baseline microbiota (no treatment for the neurotypical group). Major findings: none to report yet				
<b>15. SUBJECT TERMS</b> Autism; gastrointestinal problems; constipation; diarrhea; microbiota transplant; fecal transplant				
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>  UU	<b>18. NUMBER OF PAGES</b>  14
<b>a. REPORT</b> U	<b>b. ABSTRACT</b> U	<b>c. THIS PAGE</b> U		
			<b>19b. TELEPHONE NUMBER (include area code)</b>	

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- 1. INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

The purpose of this research is to investigate the use of a new treatment, Microbiota Transfer Therapy (MTT) for the treatment of adults with both autism and chronic gastrointestinal problems. The scope of the research involves a Phase 2 clinical trial to determine the safety and efficacy of MTT, and to investigate how to optimize the therapy to maximize benefit while minimizing risk.

- 2. KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Autism; gastrointestinal problems; constipation; diarrhea; microbiota transplant; fecal transplant

- 3. ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

**What were the major goals of the project?**

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

The original specific aims of the project are:

- 1) Conduct a multi-site, randomized, double-blind, placebo-controlled trial of MTT in 84 adults with ASD who also have gastrointestinal problems. Evaluate the efficacy of MTT in adults with ASD, including gastrointestinal symptoms and autism-related symptoms.
- 2) Evaluate the effect of MTT on gastrointestinal microbiota and biomarkers of GI health.
- 3) Compare the GI microbiota of adults with ASD vs. neurotypical controls, matched for age and gender, half of whom have similar GI symptoms
- 4) Validate the GSRS for adults with autism.

**The original milestones and target dates for year 1 and 2, and the actual completion dates or % of completion, are shown below:**

Milestone	Original Target Date	Actual Completion Date or % Completed	Actual Completion Date or % Completed
		ASU (ASD/NT)	PCH (ASD/NT)
<b>Subtask 1:</b> Submit study plans to FDA and IRBs for approval	Sept 2016-May-2017	Sept 2016-Aug 2017	same
Submit modification of IND to FDA	Sept 2016	March 2017	same
Respond to FDA	Oct 2016	March-April 2017	same
<i>Milestone Achieved: FDA approval of IND</i>	Dec 2016	April 2016	same
Submit to IRB and USAMRMC ORP HRPO	Jan 2017	May 2017 (IRB) and Aug 2017 (HRPO)	Jan 17, 2018 (IRB) and April

			27, 2018 (HRPO)
Review feedback from IRBs and USAMRMC ORP HRPO	Feb 2017	May 2017-Aug 2017	Jan 17, 2018 (IRB) and May 10, 2018 (HRPO)
Final submission to IRBs and USAMRMC ORP HRPO	March 2017	Aug 2017 (IRB); Oct 2017 to HRPO	Feb 14, 2018 (IRB) and May 11, 2018 (HRPO)
<i>Milestone Achieved: IRB and HRPO approval</i>	March 2017	Dec 2017	Feb 20, 2018 (IRB) and May 24, 2018 (HRPO)
		ASU	PCH
<b>Subtask 2:</b> Conduct clinical trial	June 2017 to Sept 2019		
Coordinate logistics at both study sites	9	Jan 2018	May 2018
Train study staff in approved protocol	9	Sept 2017	May 2018
Meeting with clinical trial monitor and research monitor	9	Sept 2017	May 2018
<i>Milestone Achieved: Research staff trained</i>	9	Sept 2017	May 2018
Advertise for participants	10-23	Jan 2018	Jan 2018
Review applications	11-24	69% / 36%	48% / 12%
Consent interested applicants	12-24	69% / 36%	48% / 12%
Collect baseline questionnaires, collect and review medical history	12-24	69% / 7%	48% / 12%
Validate ASD diagnosis with ADOS	12-24	69% / n/a	24% / n/a
<i>Milestone: Complete recruitment</i>	24	69% / 7%	24% / 12%
Begin Clinical Trial	13-25	69% / 7%	24% / 12%
Safety Monitoring Committee meets quarterly (once treatment starts)	13-36	Sept 2017; Feb 2018; Sept 2018; Dec 2018; Feb 2019; May 2019; Oct 2019; April 2020; Sept 2020	same
<i>Milestone: Complete Part 1 of clinical trial (randomized, double-blind, placebo-controlled study)</i>	27	69% / n/a	24% / n/a
<i>Milestone: Complete Part 2 of clinical trial (extension of treatment)</i>	30	69% / n/a	24% / n/a

## What was accomplished under these goals?

*For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.*

### 1) Major Activities:

- ASU: Completed 19 participants through the treatment period of the study
- PCH: Completed 10 participants through the treatment period of the study
- Update IND protocol due to COVID-19

### 2) Specific Objectives:

- Treat current participants, and continue long-term monitoring of them
- Update IND protocol due to COVID-19

### 3) Significant Results/Key Outcomes

#### ASU Site:

#### ASD Participants

972 applications

- 41 are being processed
- 30 consented and attended first clinic (Cohorts 1, 2, 3, and 4)
  - 7 disqualified or withdrawn
    - 1 disqualified due to anemia prior to treatment
    - 1 disqualified due to need for dental surgery prior to treatment
    - 2 disqualified because recent change in medication prior to treatment
    - 1 withdrawn due to dosing error by participant
    - 1 withdrawn due to AE (fainting)
    - 1 withdrew themselves prior to clinic 2 due to lack of interest
  - 19 finished Part 2
  - 4 finished Part 1 and are ready to start Part 2 when the microbiota capsules are available
- 2 consented for Cohort 5 and 2 that were disqualified at previous clinics plan to be in Cohort 5 as well.
- 1 consented but transferred to PCH to do the study due to family's preference
- 301 denied/Screen Failed/No longer interested/ No response
- 685 have not been processed yet

#### Neurotypical Participants:

694 applications received

- 182 processed
  - 21 processing
  - 15 consented
  - 35 waitlisted (female)
  - 102 Screen Fail
- 511 need to be processed (some have already been processed by PCH)
- 3 completed the study

## PCH Site:

### ASD Participants:

- 24 eligible and will be processed
- 18 consented
  - 10 completed treatment period
  - 6 waiting to start when study resumes
  - 2 lost to follow up or withdrawn
- 45 denied/screen failed/no longer interested/no response

### Neurotypical Participants:

- 760 applications received from ASU
  - 5 completed the study
  - 583 ineligible
  - 130 eligible but not age or gender matched
  - 42 no response

#### **4) Other Achievements**

- Continued meetings with our DSMB
- Updated protocol due to COVID-19

#### **5) Goals Not Yet Met**

ASU: We still need to finish four participants through Part 2, consent and treat the final 16 ASD participants, and finish the neurotypical participants.

Phoenix Children's Hospital (PCH): We need to finish recruiting for ASD and NT participants, and getting them started and through the study.

### **What opportunities for training and professional development has the project provided?**

*If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.*

Nothing to Report

### **How were the results disseminated to communities of interest?**

*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.*

Nothing to Report yet.

**What do you plan to do during the next reporting period to accomplish the goals?**

*If this is the final report, state “Nothing to Report.” Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.*

For the ASU site, we plan to continue the four participants who finished part 1 once drug becomes available. When further study drug is available, we plan to finish recruiting and treating participants.

For the PCH site, we hope to resume study activity and treatment once the study drug becomes available.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

**What was the impact on the development of the principal discipline(s) of the project?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.” Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).*

Nothing to Report Yet

**What was the impact on other disciplines?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.” Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.*

Nothing to Report Yet

**What was the impact on technology transfer?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.” Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:*

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report Yet

**What was the impact on society beyond science and technology?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:*

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report Yet

- 5. CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

**Changes in approach and reasons for change**

*Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.*

There have been 3 major changes due to SARS-CoV-2/COVID-19.

Microbiota Testing for SARS-CoV-2: The FDA has added a requirement that the microbiome donor or their stool samples need to be tested for SARS-CoV-2. So, the previous batch (batch 3) we had set aside for ASU cohort 4 could not be used at the present time. We worked with one company, CosmosID, which has developed a validated test for SARS-CoV-2 in stool. They tested batch 3 and found it to be negative for SARS-CoV-2, and we are submitting those results to the FDA once we have the final letter from the company (expected mid/late September 2020).

Microbiota Supply. Production of new microbiota capsules at the Un. of Minnesota was halted in March 2020 when the university closed all research facilities. They restarted production in July, but the halt caused some delay in restarting, so new batches are not expected until approximately Nov 2020.

Temporary changes to study protocol due to Coronavirus/COVID-19:

Due the disruption of travel and other activities due to the COVID-19 virus, we propose the following temporary changes be made to the study protocol on an “as-needed” basis as determined by the PI’s and the study physician.

For participants who are travelling long-distance to participate in the study, the following changes will be made to the study protocol for the end of Part 1 and Part 2. These changes are being made to increase the safety of the participants. There will be no change to the baseline protocol at the start of Part 1.

- 1) Physical Exam: The study physician will conduct a telehealth visit with the participant instead of an in-person visit. If there is a health concern the study physician may also request an in-person evaluation, either by themselves or by the participant’s PCP. In the latter case the study physician will either talk to the PCP or review a report by them after the in-person exam.
- 2) Blood draw: The blood draw can be done by a local laboratory (with a preference for LabCorp if available). The blood draw will include our standard safety tests (comprehensive metabolic panel and complete blood count with differential). In addition, if possible, the lab will also draw the extra blood samples for additional tests, and those samples will be shipped to ASU on dry ice.
- 3) CARS: The CARS evaluation can be done by Zoom or equivalent, so that the evaluator can speak with the participant and their evaluator and observe them, but if that is not possible then phone

interviews will be allowed. As per our standard practice, the same CARS evaluator will be used for all CARS evaluations of a participant if at all possible.

4) Leiter: It is not possible to conduct the Leiter evaluation long-distance, so this evaluation will not be conducted at those visits.

5) There may be some delays in scheduling different evaluations and sample collections, so the schedule of events may change somewhat, but the treatment duration for each medication will remain unchanged.

These changes to the protocol were added to the consent form (approved by DoD in April 2020) and all participants in treatment were informed of the changes and re consented with the new, approved form.

### **Actual or anticipated problems or delays and actions or plans to resolve them**

*Describe problems or delays encountered during the reporting period and actions or plans to resolve them.*

The major problems were the COVID-19 issues discussed above. However, we believe we will start treating new patients by Nov 2020 or earlier.

### **Changes that had a significant impact on expenditures**

*Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.*

The delays in enrolling participants due to COVID19 have substantially increased our study coordinator costs.

### **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

*Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.*

As described above, we made some changes in our study protocol due to COVID-19.

### **Significant changes in use or care of vertebrate animals.**

Not applicable.

### **Significant changes in use of biohazards and/or select agents**

No changes to report.

**6. PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**

Report only the major publication(s) resulting from the work under this award.

**Journal publications.** *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page*

*numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report yet.

**Books or other non-periodical, one-time publications.** *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report yet.

**Other publications, conference papers, and presentations.** *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (\*) if presentation produced a manuscript.*

Nothing to report yet.

- **Website(s) or other Internet site(s)**

*List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.*

Nothing to report yet.

- **Technologies or techniques**

*Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.*

Nothing to report yet.

- **Inventions, patent applications, and/or licenses**

*Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.*

Nothing to report yet.

- **Other Products**

*Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:*

- *data or databases;*
- *biospecimen collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to report yet.

## **7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

### **What individuals have worked on the project?**

*Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."*

**Name:** James B. Adams  
**Project Role:** Principal Investigator  
**Research Identifier:**  
**Nearest person month worked:** 3 months  
**Contribution to Project:** Primary author of IND and IRB documents; oversight of study  
**Funding Support:** ASU (2 months) and this DoD grant (0.75 month)

**Name:** Devon Coleman  
**Project Role:** Study Coordinator  
**Research Identifier:**  
**Nearest person month worked:** 9 months  
**Contribution to Project:** Study coordination  
**Funding Support:** this DoD grant

**Name:** Elena Pollard  
**Project Role:** Autism Evaluator and Study Coordinator  
**Research Identifier:**  
**Nearest person month worked:** 2 months  
**Contribution to Project:** Autism evaluations and assistance with study coordination  
**Funding Support:** this DoD grant

**Name:** Julie Ingram  
**Project Role:** Autism Evaluator and Study Coordinator  
**Research Identifier:**  
**Nearest person month worked:** 1 month  
**Contribution to Project:** Autism evaluations and assistance with study coordination  
**Funding Support:** this DoD grant

**Name:** Jigar Patel  
**Project Role:** Biosample collection and storage  
**Research Identifier:**  
**Nearest person month worked:** 0.7 months  
**Contribution to Project:** collected samples from participants  
**Funding Support:** this DoD grant

**Name:** Rosa Krajmalnik-Brown  
**Project Role:** co-PI  
**Research Identifier:**  
**Nearest person month worked:** 1 months  
**Contribution to Project:** advice on study design; will supervise microbiome analysis next year  
**Funding Support:** this DoD grant

**Name:** Richard Frye  
**Project Role:** Co-Principal Investigator  
**Research Identifier:** 0000-0003-4442-2937  
**Nearest person month worked:** 1.2 months  
**Contribution to Project:** Assisted with IND and IRB documents  
**Funding Support:** this DoD grant

**Name:** Sarah Vassall  
**Project Role:** Study Coordinator  
**Research Identifier:**  
**Nearest person month worked:** 8.0 months  
**Contribution to Project:** Recruiting subjects, conducting study visits  
**Funding Support:** this DoD grant

**Name:** Amanda Jensen  
**Project Role:** Study Coordinator  
**Research Identifier:**  
**Nearest person month worked:** 2.0 months  
**Contribution to Project:** Recruiting subjects, conducting study visits  
**Funding Support:** this DoD grant

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a*

*change in active other support significantly impacts the effort on the project that is the subject of the project report.*

No major changes.

### **What other organizations were involved as partners?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.*

*Provide the following information for each partnership:*

Organization Name:

Location of Organization: (if foreign location list country)

Partner’s contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner’s facilities for project activities);*
- *Collaboration (e.g., partner’s staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner’s staff use each other’s facilities, work at each other’s site); and*
- *Other.*

Organization Name: University of Minnesota

Location of Organization: Minneapolis, MN

Partner’s contribution to the project: development of Full Spectrum Microbiota, and supply of it for this project.

## **8. SPECIAL REPORTING REQUIREMENTS**

**COLLABORATIVE AWARDS:** For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

**QUAD CHARTS:** If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

**9. APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

No Appendices