Factors Affecting Rheumatoid Arthritis Patients' Decisions to Participate in Clinical Trials

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ABSTRACT. ***Objective.*** To delineate the personal, psychosocial, and disease-related factors that may influence rheumatoid arthritis (RA) patients' decisions to participate in clinical trials.

Methods. A total of 191 patients with RA were asked to participate in this survey. The questionnaire collected information on demographics, RA disease-related factors, and the importance of several factors that might influence patients' willingness to participate in clinical trials. Patients were then asked if they would consider participating in a hypothetical study.

Results. Participants were 88% female with a mean age of 40.5 years. The ethnic composition was 57% Hispanic, 25% Caucasian, 12% Asian, and 6% African American, with 71% having a family income < $20,000/year. Factors that patients considered important for participation in a clinical study included: the opportunity to help others, the possibility of improved health, early access to new therapy, the availability of free treatments, unknown side effects of the study drug, and the need to stop current therapy. There were strong correlations between the rank order importance weights between Hispanics and Caucasians, suggesting fundamental similarities in preferences. The most important factor was the opportunity to help others. In general, the more important factors were associated with preferences for trial participation.

Conclusion. This questionnaire identified factors that may affect RA patients' willingness to participate in a study. Patient participation in trials is driven by diverse factors that include altruism and the opportunity for healthcare and improved health. Consideration of these factors may facilitate the inclusion of more diverse patient populations into trials and enhance the applicability of trial results. (J Rheumatol 2005;32:2317–25)

Key Indexing Terms:
RHEUMATOID ARTHRITIS CLINICAL TRIALS PATIENT PREFERENCES TREATMENT

In clinical studies, inclusion of a heterogeneous study population is highly desirable, as it allows a more thorough understanding of disease characteristics as well as the safety and efficacy of novel interventions. Not only in the general population but also among different ethnic and socioeconomic subgroups, the generalizability of the results from clinical trials improves if the characteristics of the study population approximate those of the overall population with the same condition[1]. This is especially important for rheumatoid arthritis (RA), where studies have demonstrated a substantial influence of factors such as race, education, and socioeconomic status (SES) on disease outcome[2-4].

Accruing adequate numbers of subjects from minority groups in clinical trials is typically difficult. In accordance with ethical principles, patient participation in any clinical trial is entirely voluntary. Little is known about the processes by which patients make decisions concerning potential participation in clinical trials. Better understanding of patients' decision-making processes for study participation and the special factors, if any, that may influence minority group members' decisions could potentially increase the diversity of study populations. We investigated the personal, psychosocial, and disease-related factors that may influence patients' decisions to participate in clinical trials. We focused our analysis on Hispanics and Caucasians in order to reflect the demographics of the local population.

MATERIALS AND METHODS

Patients. From January 2003 to June 2003, consecutive patients with a diagnosis of RA enrolled at the University of California, San Diego (UCSD) Rheumatology Specialty Clinic were approached during their regularly scheduled clinic appointments and asked if they would be willing to participate in a survey. They were told that the survey addressed factors potentially important to patients when considering participation in clinical trials. They were informed that these questions were hypothetical and that they would not be enrolled in a clinical trial as a result of agreeing to participate in the survey. If they agreed to participate and provided written informed consent, they were given a survey in their preferred language of either English or Spanish. If patients declined to complete a survey, only the minimum information obvious from a cursory interaction in the office was collected (e.g., sex, race, and approximate age), as allowed by the UCSD Human Research Protection Program (HRPP). Eligibility criteria

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Accepted for publication June 27, 2005.

included the diagnosis of RA, according to the 1987 American Rheumatism Association (later American College of Rheumatology) criteria[5], and the ability to comprehend either English or Spanish. The protocol was approved by the UCSD HRPP.

The Clinical Trial Participation Survey. The questionnaire gathered demographic information on age, race, sex, level of education, household income, occupation, and marital status (Appendix, page 2324). In addition, pertinent medical history, tobacco use, family history of RA, and any prior participation in clinical trials were recorded. Regarding RA disease characteristics, the duration of RA, current and previous medications for RA, and information about prior joint surgeries were collected, as was the presence or the absence of rheumatoid factor (RF). Functional status at the time of survey completion was assessed using a modified version of the Health Assessment Questionnaire (HAQ). The patients' assessment of their pain and global assessment of their disease activity were measured using 10 cm visual analog scales (VAS). Every attempt was made to extract and confirm any missing, incomplete, or unclear answers on disease characteristics from patients' medical charts.

After collecting data on demographics and health status, information on the factors that were important to patients when considering participation in clinical trials was obtained. The Clinical Trial Participation Survey was developed in 3 stages. In the first stage, we conducted semistructured small focus groups with RA patients to delineate factors that could potentially influence patients' decisions to participate in a clinical study. These were conducted until an informational redundancy was observed. The details of each interview were analyzed and utilized to develop the first pilot questionnaire. Based on the results of these analyses, we identified 16 statements focusing on various factors that might influence patients' participation in a clinical trial.

During the second stage, a convenience sample of 114 RA patients from the UCSD Rheumatology Specialty Clinic completed the 16-item pilot version of the survey. Several factors were found to be potential advantages of being in a clinical study: the possibility of improved health, more time spent with doctors, early access to new therapies, financial incentives, and the opportunity to help others. Important factors that the majority of the patients viewed as potential disadvantages of being in a clinical study included: feeling "like a guinea pig," unknown side effects of the study drug, the need to stop their current RA medications, the possibility of receiving a placebo, the requirement of frequent visits to the research site, the need to travel to the research site, and the possibility of injections/infusions. Items statistically associated with patients' decision-making ($p < 0.01$) were identified and incorporated into the final instrument.

The final version of the questionnaire was developed in both English and Spanish. The Spanish version was backtranslated to English and checked by 2 independent native Spanish speakers to ensure accuracy of translation.

All questions in the final Clinical Trial Participation Survey were presented in the second-person format, with each statement beginning with a phrase, "With a research study," or "By being in a study," to remind patients that these were hypothetical questions. For example, "With a research study, you may get the sugar pill instead of the real medicine" or "By being in a study, you can provide information that could help other patients with the same disease." Importance was rated using a horizontal VAS, with 1 being not important, 3 being neutral, and 5 being very important. After completing ratings of all 16 factors, participants were asked, "After considering above questions, would you consider participating in a clinical research study of a new treatment for arthritis?".

Statistical analysis. Descriptive statistics were generated for the personal, psychosocial, and disease-related factors elicited in the questionnaire using JMP statistical software (SAS Institute, Cary, NC, USA). We used paired-test and Spearman's rho correlation coefficient to compare and correlate the importance rating across ethnic groups. Logistic regression was then used for associations between items' responses and patients' reported willingness to consider participation in the theoretical study. To facilitate interpretation of odds ratios, ratings of the importance of items were divided into high versus low values at the median of the distribution and analyses were repeated. To develop an overall explanatory model, we entered the divided ratings of all 16 items into a multivariate stepwise logistic regression (entry criterion $p < 0.2$, exit criterion $p < 0.1$) and identified the set of items that best explained variability in preferences for trial participation.

RESULTS

As the data from earlier surveys were analyzed to develop the final questionnaire, we will present only the data from the final version of the Clinical Trial Participation Survey.

Patient characteristics. Patient characteristics are described in Tables 1, 2, and 3. Seventy-five percent (144/191) of RA patients seen at the UCSD Rheumatology Specialty Clinic during the study period agreed to participate in the final Clinical Trial Participation Survey. Patients who completed and those who declined the survey were comparable in sex and race. However, overall, those who completed the survey were younger than decliners. The majority of the survey participants were female (88%) with a mean age (± SD) of 40.5 (± 13.2) years. The racial composition of the population was 57% Hispanic, 25% Caucasian, 12% Asian, and 6% African American. At study enrollment, the median disease duration was 7 years (interquartile range 3–15 yrs) with a mean HAQ score (± SD) of 1.07 (± 0.63). Regarding education, the majority of the participants (69%) had completed high school or had less formal education. The majority of the clinic population consisted of a lower socioeconomic class, as reflected by 71% of the participants having an annual household income < $20,000. Despite their similar disease characteristics, Caucasians and Hispanics differed significantly in their education and income, Caucasians having a higher level of completed education and annual income (Table 2).

Important characteristics of clinical studies. Among the factors that were considered potential advantages of being in a clinical study, the opportunity to help others, the possibility of improved health, early access to new therapy, and the availability of free treatments ranked the highest in importance. Patients seemed to be less concerned about the potential disadvantages of being in a clinical study, with the exception of unknown side effects of the study drug and the need to stop current therapy. The ranking and the mean values for importance weights for the different factors are shown for Caucasians and Hispanics in Table 4. Although the actual mean value differed across the ethnic groups, the ranks of these factors correlated highly, with a correlation coefficient of 0.91. In general, there were no statistically significant differences in importance weights observed between Caucasians and Hispanics.

Factors associated with patients' willingness to participate in clinical studies. Although many factors were rated as important, relatively few were associated with patients' intention to participate in a study. The majority of the par-

Table 1. Patient demographics.

	Survey Completer, n = 144 (%)	Survey Deferrals, n = 47 (%)
Age, yrs, mean ± SD	49.5 ± 13.2	54.7 ± 13.8*
Female	127 (88.1)	37 (80.4)
Caucasians	36 (25.0)	17 (37.8)
African Americans	8 (5.6)	4 (8.9)
Hispanics	82 (57.0)	16 (35.6)
Asians	17 (11.8)	8 (17.8)

* p = 0.024 by t test.

ticipants, with the exception of Asians, indicated that they would be willing to participate in a clinical study. Sixty-one percent of Caucasians, 75% of African Americans, 63% of Hispanics, and 31% of Asians agreed to participate in a study. Due to a relatively small number of African Americans and Asians in this study, logistic and stepwise multiple regression analysis focused on Caucasians and Hispanics to identify factors that predicted patients' willingness to enroll in a study (Tables 5 and 6). Differences in patients' baseline demographic characteristics such as age, sex, education, and SES did not influence their decisions to participate in a clinical trial. Differences in RA disease characteristics such as the use of various antirheumatic medications, duration of RA, HAQ score, prior participation in a clinical trial, and patients' global assessment of their pain and disease activity also failed to predict patients' willingness to participate in a clinical study.

Among the 16 factors related to clinical trials addressed

Table 2. Socioeconomic characteristics of survey completers (n = 144).

	All Participants, n = 144 (%)	Caucasians, n = 36 (%)	Hispanics, n = 82 (%)
Completed level of education*			
Grade school	33 (23)	2 (5.5)	26 (31.7)
Junior high school	19 (13)	0 (0)	18 (22.0)
High school	47 (33)	17 (47.2)	22 (26.9)
Junior college	17 (12)	10 (27.8)	5 (6.1)
College	22 (15)	6 (16.7)	7 (8.5)
Postgraduate	1 (1)	1 (2.8)	0 (0)
No answer	5 (3)	0 (0)	3 (3.7)
Marital status			
Single	48 (33)	12 (33.3)	28 (34.1)
Married	55 (38)	11 (30.5)	33 (40.2)
Divorced	22 (16)	11 (30.5)	9 (11.0)
Widowed	15 (10)	1 (2.8)	9 (11.0)
No answer	4 (3)	1 (2.8)	3 (3.7)
Annual income**			
< $20,000	101 (71)	24 (66.7)	60 (73.2)
$20,000–40,000	11 (8)	3 (8.3)	7 (8.5)
$41,000–70,000	5 (3)	4 (11.1)	1 (1.2)
$71,000–100,000	1 (1)	1 (2.8)	0 (0)
> $100,000	2 (1)	2 (5.6)	0 (0)
No answer	24 (17)	2 (5.6)	14 (17.1)

* p < 0.0001 between Caucasians and Hispanics (t test); ** p = 0.0177 between Caucasians and Hispanics (Welch ANOVA test).

Table 3. Disease characteristics of survey completers (n = 144).

	All Participants, n = 144	Caucasians, n = 36	Hispanics, n = 82
Disease duration, median yrs	7 (3–15 IQR)	8 (3–16 IQR)	7 (3–13 IQR)
HAQ, mean ± SD	1.07 ± 0.63	1.11 ± 0.58	1.05 ± 0.66
VAS pain, mean ± SD	4.87 ± 2.85	4.60 ± 2.76	5.05 ± 2.96
VAS global, mean ± SD	4.66 ± 2.59	4.49 ± 2.55	4.64 ± 2.70
Seropositivity for rheumatoid factor, % (RF+/RF available)	83.1	82 (18/22)	89 (47/53)
Current use of prednisone, %	47.2	25	55
Total no. of DMARD tried, mean ± SD	2.15 ± 1.18	2.44 ± 1.38	2.13 ± 1.11
Current use of TNF-α inhibitors, %	25	33	24

IQR: interquartile range.

Table 4. Patient's attitudes towards characteristics of a clinical trial.

Rank	Caucasians, mean score ± SD	Hispanics, mean score ± SD
1	Opportunity to help others, 4.70 ± 0.58	Opportunity to help others, 4.52 ± 0.92
2	Potential for improved health, 4.56 ± 0.69	Earlier access to therapy, 4.42 ± 1.00
3	Free treatment, 4.27 ± 1.00	Potential for improved health, 4.40 ± 1.02
4	Need to stop current therapy, 4.05 ± 0.94	Free treatment, 4.40 ± 0.93
5	Earlier access to therapy, 3.99 ± 1.25	Unknown side effects, 4.25 ± 1.08
6	More doctor visits, 3.96 ± 1.03	More doctor visits, 4.15 ± 1.05
7	Unknown side effects, 3.91 ± 1.13	Need to stop current therapy, 4.14 ± 1.12
8	More time spent with doctors, 3.82 ± 0.97	Free blood tests, 4.06 ± 1.18
9	Doctor trust, 3.79 ± 1.11	More time spent with doctors, 4.00 ± 1.22
10	Extra blood tests, 3.69 ± 1.21	Need to travel to research site, 3.86 ± 1.23
11	Free blood tests, 3.57 ± 1.45	Potential for placebo, 3.83 ± 1.26
12	Potential for placebo, 3.55 ± 0.96	Doctor trust, 3.73 ± 1.20
13	Need to travel to research site, 3.48 ± 1.11	Extra blood tests, 3.71 ± 1.30
14	Potential for infusions/injections, 3.25 ± 1.38	Potential for infusions/injections, 3.71 ± 1.26
15	Potential to get paid, 3.16 ± 1.39	Potential to get paid, 3.45 ± 1.38
16	Feeling like a "guinea pig," 3.05 ± 1.23	Feeling like a "guinea pig," 3.28 ± 1.30

Spearman rho correlation between 2 group mean ranks 0.91, $p < 0.0001$.

Table 5. Factors that predicted patients' willingness to participate in a clinical trial: logistic regression. Participants divided into 2 groups: below the median and equal to or above the median.

Factors	OR for All Participants (95% CI)	OR for Caucasians (95% CI)	OR for Hispanics (95% CI)
Free blood tests	3.66 (1.82–7.53)*	7.86 (1.81–43.86)*	2.79 (1.07–7.40)*
More doctor visits	3.39 (1.68–6.99)*	1.08 (0.27–4.24)	4.96 (1.86–13.98)*
Opportunity to help others	3.21 (1.57–6.69)*	10.00 (1.91–79.00)*	2.47 (0.96–6.50)
Earlier access to therapy	2.95 (1.48–6.01)*	16.00 (3.21–125.12)*	1.90 (0.73–4.95)
Free treatment	2.67 (1.33–5.44)*	3.86 (0.97–17.04)	2.43 (0.95–6.39)
More time spent with doctors	2.52 (1.26–5.10)*	3.40 (0.82–15.38)	1.46 (0.57–3.75)
Potential for improved health	2.48 (1.24–5.08)*	14.25 (2.92–91.93)*	1.65 (0.63–4.31)
Doctor trust	0.93 (0.46–1.85)	0.19 (0.03–0.80)*	1.22 (0.47–3.21)
Unknown side effects	0.72 (0.36–1.45)	0.17 (0.03–0.71)*	0.95 (0.35–2.45)
Need to stop current therapy	0.60 (0.30–1.18)	0.11 (0.02–0.51)*	0.77 (0.29–1.98)
Need to travel to research site	0.56 (0.28–1.10)	0.09 (0.01–0.41)*	1.13 (0.45–2.85)
Extra blood tests	1.76 (0.89–3.51)	1.00 (0.26–3.88)	2.21 (0.87–5.79)
Feeling like a "guinea pig"	0.78 (0.32–1.80)	0.82 (0.10–4.95)	0.76 (0.24–2.21)
Potential to get paid	1.63 (0.72–3.72)	2.50 (0.54–12.44)	1.18 (0.36–3.59)
Potential for placebo	1.10 (0.38–3.07)	Unstable statistics	1.07 (0.26–3.93)
Potential for infusions/injections	1.24 (0.63–2.48)	0.38 (0.09–1.51)	1.87 (0.73–4.91)

* OR: Odds Ratio with 95% confidence interval and $p < 0.05$.

Table 6. Factors that predicted patients' willingness to participate in a clinical trial: stepwise multiple regression (Asians, African Americans, and other race excluded).

Factors	OR (95% CI)*
More doctor visits	5.87 (1.62–25.78)
Free blood tests	4.15 (1.23–15.84)
Unknown side effects	0.28 (0.07–0.95)
Need to stop current therapy	0.23 (0.06–0.73)
Need to travel to research site	0.21 (0.05–0.75)

* All $p < 0.05$.

in this study, most of the factors that were considered potential advantages of being in a clinical study also predicted patients' willingness to participate in a clinical study. These included the possibility of improved health, early access to new therapy, the opportunity to help others, free treatments, free blood tests, and the opportunity to spend more time with physicians, both in the number of visits and in the duration of each visit. All patients, regardless of race, were positively influenced by these factors to participate in a clinical trial, with Caucasians having significantly higher odds

ratios than Hispanics. Interestingly, there were some racial differences regarding factors considered potential disadvantages of being in a clinical study. Caucasians were more likely to decline trial participation because of the lack of trust in doctors, unknown side effects, the need to travel to a research site, and the potential need to stop their current RA therapy (Table 5). In stepwise multiple regression analyses, more doctor visits and free blood tests positively predicted patients' willingness to enroll in clinical trials, whereas unknown side effects, need to stop current therapy, and the need to travel to research sites negatively influenced patients' decisions to participate in clinical trials (Table 6). A combination of these factors accounted for 30% of the variance in this model. Overall, Asians were less willing (65%) to participate in a clinical trial than other races. However, due to a small sample size (n = 17), it remains unclear why and which factors significantly influenced their decisions to decline enrollment in a clinical trial.

DISCUSSION

Clinical research is an essential tool for providing information on safety and efficacy of new therapies for many medical conditions, including RA. In addition, for those patients whose resources are limited, for example due to socioeconomic considerations, clinical research may provide a means by which they can have access to new therapies at no additional cost. Yet in subspecialty research areas such as human immunodeficiency virus (HIV) and oncology, a lower participation rate in clinical trials among minorities has been observed[6-8]. For example, although African American men have a higher prevalence of prostate cancer, they made up only 4% of the 18,882 total study sample in the Prostate Cancer Prevention Trial[8]. In many cases, it is difficult to even assess the extent of minority representation in published studies. For instance, among 253 eligible clinical trials published in 3 major internal medicine journals that focused on areas with known health disparities among race (e.g., HIV, diabetes, cardiovascular diseases, and cancer), only 46% of the trials reported patient participation or results by race[9].

Similarly, a lower participation rate among minorities has also been noted in recent studies that have significantly shaped our management strategies in RA. For example, although African Americans and Hispanics each make up 12% of the US population, each subgroup represented less than 5% of the total study population in several notable studies[10-14]. In other studies, the racial composition of the study population is unknown. If such data were collected, it is not reported in the publication of many important RA studies[15-18]. Thus, it is largely unknown if contemporary clinical research on RA adequately reflects the overall RA population in terms of race, education, and SES.

In disciplines outside of rheumatology, several studies conducted to investigate the racial discrepancy in the rate of participation in clinical trials have identified some racial differences in patients' preferences towards clinical trials. For example, African Americans and Hispanics have expressed distrust in physicians and clinical trials as one of the key factors discouraging their participation in clinical trials[19-25]. In part, it has been suggested that this distrust may stem partially from their knowledge of historical events such as the Tuskegee Study[19]. Interestingly, in one study, the percentage of minority patients who expressed willingness to participate in clinical trials was often higher than the actual percentage enrolled in clinical trials. These responders expressed their insufficient knowledge about the availability of ongoing trials as one of the major barriers to their participation[20]. In a subset of patients, lower expectations in benefits seemed to further discourage their participation[26]. In one study, an education level higher than high school, independent of race, positively correlated with patients' willingness to participate in clinical studies[19].

Currently, although there are numerous clinical trials assessing various novel therapeutic agents for RA, there are very few studies specifically looking into factors that may influence RA patients' preferences and attitudes towards clinical research. In one study conducted prior to the wide availability of biologic agents, it was found that patients with RA who had participated in clinical trials seemed similar to the overall group of patients with RA in a clinic with regard to factors that might affect study participation[27]. Differences in patient demographics, associated comorbidities, and the severity of disease burden prevent extrapolation from disciplines outside rheumatology to patients with RA. Therefore, we designed a cross-sectional survey to delineate the personal, psychosocial, and disease-related factors that may affect RA patients' decisions to participate in clinical trials. In addition, we attempted to validate if those factors found to be significant in other subspecialties were also significant for RA patients who were considering participation in a clinical trial.

This Clinical Trial Participation Survey, given to 191 consecutive patients with RA seen at the UCSD Rheumatology Specialty Clinic from January 2003 to June 2003, identified some factors that predicted patients' willingness to participate in clinical trials. The potential for improved health and earlier access to new therapy significantly predicted patients' willingness to participate in clinical trials. Financial incentives, in the form of free treatments and blood tests, along with an opportunity to spend more time with physicians, in both number of visits and duration of each visit, were also significantly associated with patients' decisions to enroll in clinical trials. Despite the popular belief that patients often decline to participate in a study due to a sense of "feeling like a guinea pig," it ranked among the lowest for importance weights for study characteristics. Indeed, patients' decisions were more influenced by the "opportunity to help others." Interestingly, altruism

also proved to be an important motivating factor for RA patients in a previous study[27]. Unfortunately, studies into the role of altruism in patients' decisions to participate in clinical trials are sparse.

Of note, factors that played an important role in other studies[19-27], such as trust in physicians and education, failed to predict RA patients' willingness to participate in a clinical trial in this study. However, among Caucasians participating in our study, trust in physicians negatively correlated with their willingness to participate in clinical studies. In addition, monetary payment had no influence on RA patients' preferences regarding trial participation, regardless of their race.

We hypothesized at the start of the study that there could be important differences between ethnic groups' motivating factors for enrollment in clinical trials. Our study was limited by a small number of Asian and African American participants, which prevents us from drawing conclusions about differences between these subgroups. While there were minor variations in importance ratings assigned by Hispanics and Caucasians, both groups essentially had the same rank order for importance weights for trial factors (Spearman rho of 0.91). However, there were differences between Caucasians' and Hispanics' factors in linkages between importance weights and preferences for participation in trials. Caucasians' willingness to participate in a clinical trial was positively associated with the importance weights given to the earlier access to therapy, and potential for improved health, while it was negatively associated with unknown side effects of the study drug, the potential need to stop their current RA medications, and the need to travel to research sites. In contrast, Hispanics' willingness was positively associated with other positive factors, such as doctor visits and free laboratory tests, but there were no negatively associated factors. Thus it is unlikely that fear of adverse effects, distrust, or other negative factors are the cause of low rates of participation of Hispanics in clinical trials. Rather, these data suggest that Hispanics may not be aware of the potential benefits of a clinical trial. Caucasians may consider personal aspects of a study, such as the possibility of improved health and the unknown side effects of a study medication, to a greater extent than do Hispanic patients with RA, who may focus on advantages from a more intensive healthcare process used in clinical trials.

In this pilot study, only global factors that might influence patients' decisions to participate in clinical research in a global way were addressed. Study-specific factors (e.g., mode of medication delivery, side effect profile) that are also likely to play a role in patients' decisions to participate in specific types of clinical trials were not fully addressed with this questionnaire. Nonetheless, this pilot study demonstrates that there are racial differences in global factors affecting patients' preferences towards clinical trials.

Finally, our study was also limited by the overrepresentation of patients (71%) with lower SES with an annual income of < $20,000, consistent with the overall makeup of our clinic. Thus, the results can only be extrapolated or applied to those of similar SES. Although our sample population does not reflect the SES makeup of the general population, it reflects a group that is often underrepresented in clinical trials, namely Hispanics.

This questionnaire will need to be further tested for its reproducibility and construct validity.

Consideration of ethnic-specific factors during the recruitment process may facilitate inclusion of a more diverse study population and enhance the applicability of the study results to a greater subgroup of patients.

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Appendix I. Clinical Trial Participation Survey

CIT Rheumatoid Arthritis (RA) Demographic Questionnaire

Name: _____ Date: _____
Address _____ Zip Code: _____
Home Phone: _____ Work Phone: _____

Race: Caucasian ☐ African American ☐ Hispanic ☐ Asian ☐ Other: _____

Sex: Female ☐ Male ☐ Date of Birth: ___/___/_____
Highest Completed Level of Education:
Grade School ___ Junior High School ___ High School ___
Junior College ___ College ___ Post-Graduate ___

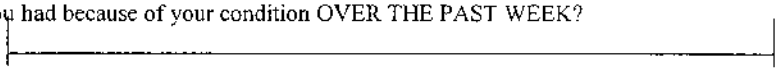
Location of your Arthritis Clinic:
Hillcrest ___ St Vincent/DePaul ___ Thornton ___
How far do you live from your arthritis clinic (in miles)? _____

Current Occupation: _____ Prior Occupation: _____
Marital Status: Single ☐ Married ☐ Divorced ☐ Widowed ☐
Approximate total household income per year:
< $20,000/yr ___ $21,000 - $40,000/yr ___ $41,000 - $70,000/yr ___
$71,000-$100,000/yr ___ > $100,000/yr ___

Please check the one answer that describes your ability to do these activities at this time.

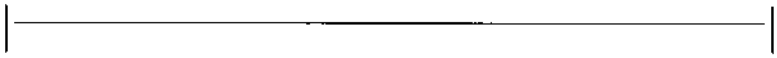
AT THIS MOMENT, are you able to:	Without ANY Difficulty	With SOME Difficulty	with MUCH Difficulty	UNABLE To Do
a. Dress yourself, including tying shoelaces and doing buttons?				
b. Get in and out of bed?				
c. Lift a full cup or glass to your mouth?				
d. Walk outdoors on flat ground?				
e. Wash and dry your entire body?				
f. Bend down to pick up clothing from the floor?				
g. Turn regular faucets on and off?				
h. Get in and out of car, bus, train or airplane?				
i. Walk two miles?				
j. Participate in sports and games, as you would like?				

How much pain have you had because of your condition OVER THE PAST WEEK?



No pain — Pain as bad as it could be

Considering all the ways in which illness and health conditions may affect you at this time, please make a mark below to show how you are doing.



very well — very poorly

Name: _____ Date: _____

Rheumatoid Arthritis
Date of diagnosis: ___/___/_____ Date when joint pain started: ___/___/_____
Date of any joint surgeries:
Presence of rheumatoid nodules (i.e. on elbows?)

Medications:

Name	Current Use	Start date	Past Use	Stop date	Duration	Why stopped?
Prednisone/ Deltasone						
Methotrexate/ Rheumatrex						
Leflunomide/ Arava						
Hydroxycholoroquine/ Plaquenil						
Sulfasalazine/ Azulfidine						
Gold shots						
Etanercept/ Enbrel						
Infliximab/ Remicade						
Anakinra/ Kineret						
Azathioprine/ Imuran						
Cyclosporin/ Neoral						
Cyclophosphamide/ Cytoxan						
Others:						

Past medical history

History of cancer? If so, what type? Date diagnosed and the treatment received.

History of heart attack or heart disease? If so, when and any surgeries for it?

History of tuberculosis (TB)? Ever been treated and if so, for how long?

Family history of rheumatoid arthritis?

History of cigarette use? If yes, #packs/day ____ #of years ____

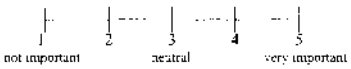
For women:
Ever been pregnant? If so, when and how many times? How many deliveries?

When was your last menstrual period? If not, when did you start menopause?

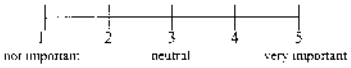
Questions
Please read and answer the following questions using the scale provided.

These are some of the things a person may think about when deciding to participate or not in a study. How important are they for you?

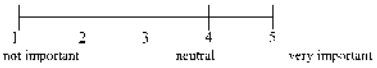
1) With a research study, you can get the newest treatments early.



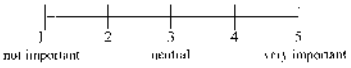
2) With a research study, you may get a sugar pill instead of the real medicine.



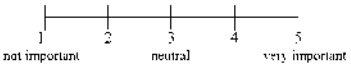
3) By being in a study, you can provide information that could help other patients with the same disease.



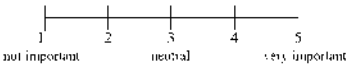
4) With a research study, you may need to see the doctor more often.



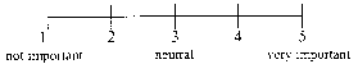
5) With a research study, you can get expensive new treatments for free.



6) With a research study, you may have to travel to a specified research facility.



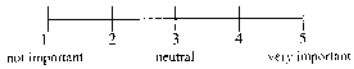
7) With a research study, you can get free blood tests and doctor visits



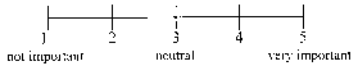
8) In a research study, the medicine may require an injection or an infusion.

9) With a research study, you get to spend extra time with the doctor.

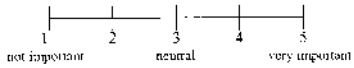
10) With a research study, your health may improve more than it would with normal medications.



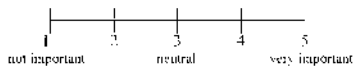
11) With a research study, you may need to give extra blood tests.



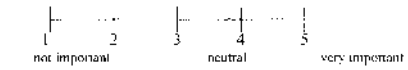
12) With a research study, you may feel like a "guinea pig."



13) Your doctor may or may not want you to be in a study

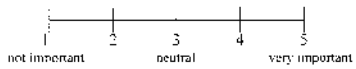


14) With a research study, you may get paid.



15) In a research study, drug therapies may not have been approved by the government and may have unknown side effects.

16) With a research study, you may need to stop some of your current medicines.



* After considering above questions, WOULD YOU CONSIDER PARTICIPATING IN A CLINICAL RESEARCH STUDY OF A NEW TREAMENT FOR ARTHRITIS?

Yes ☐ No ☐

Have you ever been in a clinical research study?

Yes ☐ If so, when? _____ No ☐