

The Wizard of Irb

Research Fables from the Sisters Grinn, No. 10

By Jeanne Grace, PhD, RN

Abstract: I started writing the fables in 1996, when I took over teaching the undergraduate research course. At first, they were "buried treasures" hidden in the on-line course materials (it was a hybrid course, and we were trying to get the students to develop internet surfing skills) for students to find. Then, as there were more of them, I started explicitly assigning them for student reading. As I've had time, I've written fables for areas where students seem to get "stuck" on basic concepts in research. Two of the fables have "readers' theater" versions that I use in class for traditional students. Casting the parts is always fun. Enjoy!

The entire series of Dr. Grace's research fables are available in this repository. Patrons may access the series by clicking on Dr. Grace's name in the item record.

The Wizard of Irb



orothy Gale was a young but promising principal investigator of clever clinical trials in the duchy of Ethical Research. As she endeavored to pursue her research, however, she encountered an unending torrent of obstacles. Her grant budgets were summarily reduced by governmental funding agencies. The paperwork and reporting requirements at her institution seemed ever to increase. And her colleagues in commercially-sponsored research threatened to shut her out of clinical trials if she

couldn't obtain human subjects approval faster than competing sites.



Beset by such burdens, Dorothy decided to take her little dog Nono and inspect her research activities from her survey ship, Good Intentions. She had scarcely begun her trip when ominous clouds appeared. Around her thundered the demands "Faster, cheaper, more!" and jagged lightning split the darkening sky. The Good Intentions began to sway and lurch. Looking at her instrument panel, Dorothy was amazed to discover that the Profile of Mood States was wavering wildly, the CD4 count was down, and the State Trait Anxiety Index was pegged at its highest level. Locus of control did multiple flipflops as the Good Intentions was pulled into the maelstrom and flung about by the winds.

Amidst the battering and buffeting in the dark skies, Dorothy and the Good Intentions lost track of both direction and time. Finally, when it seemed the ship could stand no more, the winds lessened abruptly and the Good Intentions landed with a jarring thump. Shaken, Dorothy roused herself to assess the situation. Good Intentions was badly damaged and [unlikely](#)¹ to travel again without major repairs. Nono, thankfully, was frightened but otherwise not visibly injured. Dorothy picked up the little dog and climbed out of the wreckage.

Dorothy found herself in the central square of a quaint rural village. Above the rustic buildings, the sky was calm and blue, with wispy fair weather clouds partially obscuring the suns (one red, one green). Almost immediately, a veritable posse of petite persons poured into the square. They were jubilant -- jumping up and down joyfully and chanting, "No more phony data!" "Goodbye, deliberate wrong conclusions!" "Farewell, plagiarism!" They were also cheering for a somewhat bewildered Dorothy. "Nono," she said, "I don't think we're in Ethical Research anymore."

At length, the jubilant commotion diminished as a plumply petite personage of particular importance came forward and stood in front of Dorothy. "I am the division chief of OPRRyland. On behalf of our residents, I hereby welcome you and thank you for your visit. We are so grateful you came to solve our problem!"

Dorothy took a quick mental inventory of her current research endeavors. Offhand, she couldn't think of a single clinical problem she was investigating that had relevance to rural villages or petite adult personages, so she was carefully noncommittal. "Thank you for your warm welcome. I do hope the unplanned landing of Good Intentions has not done any damage."

"Quite the opposite," bubbled the division chief. "All of us here are human subjects protection specialists, clinical site auditors and data safety monitoring committee members. Your craft's lucky landing has destroyed our lifelong foe, the Malevolent Occult Personage (MOP) of Scientific Misconduct. We are eternally in your debt!"

With horror, Dorothy followed the deputy director's gaze. Sticking out from under the ruins of Good Intentions were a pair of legs, with feet clad in bright red running shoes that glistened and glimmered in the sunlight. "But I didn't mean to hurt anybody! It was an accident! Why didn't the MOP get out of the way? Couldn't you see the Good Intentions coming?"

"Oh, we all saw you coming," said the deputy director. "But the MOP thought you were adverse findings that would have affected the study sponsor's stock price and deliberately avoided analyzing the data. True to Scientific Misconduct to the very last, I must say."

Dorothy's survey of the external damage to Good Intentions was interrupted by the arrival of a motorcycle in the town square. The rider was obviously well known to the celebrating townsfolk, who greeted her with excited descriptions of the Good Intentions' arrival. The newcomer dismounted and walked over to Dorothy. "I am the Benevolent Occult Personage of the Southern North, Belmont, and [Helsinki](#) , ² but you can call me Jane. I came in response to the telephone notification of a serious adverse event, specifically a possible research-related death, and I commend the division chief for such prompt reporting."

"I'm really sorry about the MOP," said Dorothy, "but I don't think this adverse event was related to my research at all."

"On the basis of what the witnesses tell me, " said BOP Jane, "I'd agree. I see no need to suspend your research activities, although I will conduct a complete investigation of this incident."

The mention of possible research suspension jolted Dorothy back into awareness of her continuing concerns. Her tenure review was coming all too soon, and she needed to wrap up her current research projects and get out some manuscripts and new grant proposals. She couldn't afford to be away from her clinical trials any longer. "Jane, I need to get home right away. Can you tell me how to get back to Ethical Research from here?"

As if on cue, a swirling darkness covered a sun (the red one) and resolved itself into an approaching flying object. The townsfolk cowered and cried out in dismay as they recognized the MOP of Disrespect for Persons. Landing with an untidy crash in front of Dorothy, the MOP screamed. "You squashed my dearest friend! I'll see to it you and your little dog never get home!"

The violence of the verbal assault frightened Dorothy, but Jane stepped forward in front of the angry MOP. "Time for a reality check. The Misconduct MOP caused her own problem. We need to move on." Jane gestured, there was a sudden flash of light, and Dorothy discovered that her feet now wore the Misconduct MOP's gaudy shoes.

The resultant fury propelled the Disrespect MOP back into the sky. "The Ruby Reeboks! I'll get you yet! You'll never defeat me!" The MOP's screams faded as she disappeared from view.

Dorothy was shaken, and Nono was trembling in her arms. "The Malevolent Occult Personage of Disrespect for Persons is a strong enemy, and we must always be vigilant in defense. But the MOP cannot hurt you while you wear those shoes," said Jane.

"Oh, Jane. I just want to go home. Can you tell me how to get back to Ethical Research?" begged Dorothy.

"Sadly, the details are not within my job description. But the Wizard of IRB will know. You must go to IRB and ask the Wizard's help."

"How do I get to IRB?"

"Some people download the application forms and submit three copies of the proposal summary, the grant face sheet, and evidence of peer scientific review. But I think you'd be well advised to appear in person. Route CFR 46 begins at the edge of OPRRyland, and it will lead you directly to IRB and the Wizard. The townsfolk of OPRRyland will provide you with provisions for the journey. The path is long, but well-marked with small, self-adhesive memo forms. All you need do is follow the 'yellow sticky' road."

Dorothy's eagerness to get home was such that she declined any further celebration in OPRRyland and set out for IRB as soon as food and drink for her journey could be [gathered](#). ³ CFR 46 was well-marked and ran through lovely, gently rolling countryside. The suns shone brightly, and Dorothy's newly-acquired footwear seemed to add spring to her step. She began to jog, with Nono at times trotting beside her, and at times running ahead.

Nono was almost out of sight around a gentle bend when the little dog stopped and began to bark. A straw figure dressed in ragged clothes was waving on a post in a nearby field, and Dorothy realized with some surprise that there was no breeze to explain the movement. She stopped for a closer look and was amazed to hear the figure call for help.

"Please get me down! A gang of clinical investigators targeted me as a subject for their hay fever research because I'm poor and can't afford conventional treatment. The research had no possible benefit to me, only to their friends who could pay for the therapy they were testing. When I asked to withdraw, they stranded me here."

Dorothy had always had a soft spot in her heart for vulnerable subjects, and she was indignant about the treatment the straw person, whose name turned out to be Effie Jee, had apparently received. She lifted Effie off the post, then supported her as she regained her balance. "How else can I help you?" she asked.

"All I need or want is a little justice," replied Effie. "Fair's fair, and the people who will receive the benefits of research should be the ones to bear the risks, too."

Dorothy looked troubled. In her own land, she would have reported a concern about research subjects' rights to the designated institutional representative for investigation. But she had no idea how to proceed here. Then her face brightened. "I know, you can come with me to see the Wizard! If he can tell me how to get back to Ethical Research, he can surely tell you how to get justice." Effie eagerly agreed to the journey and buoyed by Dorothy's confidence, the travelers set out again.

They had barely regained a steady pace when a large, shaggy creature jumped out at them from behind a nearby rock. Nono began to bark, and the creature answered with a roar that was so unconvincing, Dorothy found herself laughing. The creature pulled itself up with offended dignity. "I am Lie-In Woods, the mighty feral feline of these parts. It is impolite to make fun of me!"

Nono gave a single yip, and Lie-In jumped backwards a foot and cowered. Tears welled up in the great cat's eyes. Again, Dorothy's heart softened to see such distress. "How did you come to this wretched state?" she asked.

"I was in a behavioral research project while I was enrolled in advanced feline training. All the researchers told me was that they were studying learning, and I had to "volunteer" if I wanted a good grade in Basic Prey Stalking. They pressured me to bite other species to see if I would develop taste preferences. I did develop a taste for persons, but I'm so conflicted about it I can't even hunt! And to make matters worse, they identified me in their report, so all the animals know about my problem. What I want is respect for persons, instead of an appetite for persons. I'm sure that would solve my problems!"

Dorothy's anger at the researchers in this strange land increased. "Didn't the researchers offer you any help to recover from the effects of their experiment?" she asked. Lie-In sadly shook his mane from side to side. "Well," said Dorothy. "You may as well come with us. We're off to see the Wizard, to see if he can help me get back to Ethical Research and find some justice for Effie. Perhaps the Wizard can give you respect for persons, too."

So off they all went down the yellow sticky road. Lie-In had once been in IRB and told the others that it was a splendid, glittering city that shone in the sun like sapphire. The travellers could not yet see the city in the distance, and the suns were high in the sky. Since Dorothy had some concern about Lie-In's behavior, should he become too hungry, she suggested they stop in a grove of trees to share a picnic lunch. They unpacked the provisions from OPRRyland and were eating a peaceful lunch when they heard loud screeching from someplace nearby.

Dorothy looked around the grove. There was something peculiar about one of the trees in the deepest shadow. Upon closer inspection, she realized it wasn't a tree, but rather a crudely constructed robot. The outer shell was streaked with rust, and the robot's strenuous efforts resulted in much noise and little movement. Somehow, the robot conveyed desperation with its frozen face. "Uhhhl," it said through clenched jaw.

"What?" asked Dorothy.

"I think it's asking for oil," said Effie. "I'll bet its oil can is somewhere nearby." Lie-In cast about in the bushes, found the can, and applied the contents liberally to all the robot's joints. Gradually, the robot's intended range of motion returned.

"Ah! That is so much better!" said the robot. "Thank you, thank you, for rescuing me from my plight! Allow me to introduce myself. I am the New and Improved Household and Commercial General Purpose Utility Android, Version 10.0, but my friends just call me 'Ten'."

"I assume your dilemma was research-related?" queried Dorothy.

"How did you guess?" said Ten. "I was participating in a clinical trial of diet and atherosclerosis, and the researchers insisted on a no-oil washout period between the trials of mono-unsaturated and poly-unsaturated fats. They said I might experience some stiffness, but they certainly didn't warn me how bad it would really get! We androids need to know what oil is best for us to use, but there's no reason we need to suffer so in the process."

"Sounds to me", said Dorothy, "as if you're interested in seeking beneficence."

"Exactly!" agreed Ten.

"Well, we're all on our way to see the Wizard of IRB. Effie wants justice, and Lie-In wants respect for persons, and I want to get back to my home in Ethical Research. BOP Jane said the Wizard could [help](#) .⁴ You are welcome to join us on the journey."

Ten agreed, and the party of seekers walked on through the hills and meadows of IRB. At last, as the suns were hanging low in the sky, they sighted a glittering city in the distance. "There it is!" cried Lie-In. "The Sapphire City of IRB!" The travelers quickened

their pace and soon stood in front of the open city gates.

IRB was even more lovely than Dorothy could have imagined. In the late day sunshine, the city seemed not just to reflect light, but to glow from within. As luck would have it, the Wizard was holding a public audience. Dorothy and the others followed the crowd to the Temple of Empirical Knowing. Lie-In managed a mostly-convincing roar, and the crowd parted enough to allow Dorothy and her companions to move to the front. The Wizard's imposing image was displayed on multiple large screens around the hall as he answered questions posed by citizens at one of the microphones in the aisles. Dorothy joined the line at a microphone and had been waiting her turn for several minutes before she realized that the Wizard's true location could not be seen. At last, it was Dorothy's turn to speak.

"Sir" began Dorothy, "my name is Dorothy Gale and I am from Ethical Research. I accidentally landed here when my ship Good Intentions crashed, resulting in the death of the MOP of Scientific Misconduct. BOP Jane said you could help me get back home. And these are my friends, who want to know if you can help them find justice, respect for persons, and beneficence. Will you help us, please?"



The audience chamber, which had maintained a steady hum of conversation through the prior requests for tax relief, protective tariffs, and declarations of official days and weeks, was suddenly silent.

"WHAT DID YOU SAY?"

"I said, 'Sir, my name is Dorothy Gale and I am from Ethical Research. I accidentally landed here when my ship Good Intentions crashed, resulting in the death of the MOP of Scientific Misconduct. I want to go back home. And these are my friends, who want to know if you can help them find justice, respect for persons, and beneficence.' Can you help us?" Dorothy repeated.

"YOU KILLED A MOP?"

"Well, I guess so. It was an accident. Good Intentions landed right on top of her."

There was a long, almost unbearable, period of silence.

"ARE THOSE THE RUBY REEBOKS ON YOUR FEET?"

"That's what the MOP of Disrespect for Persons called them."

"YOU SURVIVED AN ENCOUNTER WITH THE MOP OF DISRESPECT FOR PERSONS, TOO?"

Although Dorothy had been initially awestruck by the Wizard's image and voice, her impatience -- and thus her boldness -- was returning. "Can you help us or not?"

"FIRST, BRING ME THE DISRESPECT MOP'S LAPTOP COMPUTER -- THE ONE WITH THE INFERNAL CONSENT THESAURUS SOFTWARE. THEN I WILL HELP YOU AND YOUR FRIENDS."

The giant screens suddenly went dark, and the sound system echoed with the announcement that the Wizard had left the building. The crowd began to drift out of the audience chamber into the green twilight (the red sun set first).

Dorothy was near tears. It had been a very difficult day. She was now expected to face the MOP of Disrespect for Persons again, and she didn't even know how to find her, much less obtain the consent software. Her own disappointment was mirrored in the faces of her new friends, and even Nono looked dejected.

A small number of people remained in the audience chamber, and they now approached Dorothy and her friends. "Can we help you? We're Local Informants, and we're supporters of Ethical Research. Allow us to shelter you for the night and provide guidance for your new and important quest." Dorothy accepted, and the seekers spent the night in careful planning and restless slumber.

The next day was full of ominous portents. Both suns rose briefly, apparently thought better of it, and retreated back beyond the horizon. Dark clouds raced overhead, and a raw, cold wind howled around IRB. Fortified with warm parkas and all the information the Local Informants could provide, Dorothy and her friends set off down the road leading to the Disrespect MOP's stronghold. Behind them, IRB disappeared from view.

The road was rough, and Dorothy became convinced the very land was resisting their forward progress. Roots and rocks tangled their feet and branches snatched at their clothes. As the MOP's stronghold came into sight, Dorothy was dismayed to see a horde of flying creatures issuing from the tower. The MOP's minions were attacking! "What are those things?" she gasped.

"Jargon soldiers!" replied Ten. "They defy respect for persons by writing consent forms in language few subjects can understand. They see no evil, hear no evil and speak no clarity. They get their power from the Infernal Consent software. Without it, they're powerless. That's why the Wizard wants you to get the laptop. You must cover your

ears, Dorothy! Quickly, before their language corrupts you!"

The flying jargon soldiers were upon them. Dorothy covered her ears against their babble. There was great confusion, then silence. The jargon soldiers were gone, carrying away Effie, Lie-In, Ten, and even Nono. Dorothy was alone on the road.

The demands of the moment helped Dorothy overcome her shock at the loss of her friends. Dorothy recalled that BOP Jane had said the MOP couldn't hurt her while she wore the Ruby Reeboks. Apparently, the protection extended to attacks from the MOP's jargon soldiers, as well. All Dorothy's desires -- from the safety of her friends to her return to Ethical Research -- demanded that she gather her courage and face the MOP. Resolutely, she continued on the road to the stronghold.

Dorothy's face was grim and her pace was steady. A small flock of jargon soldiers landed on the path ahead of her. "Patients in this trial will undergo serial phlebotomy for pharmaceutical agent pharmacokinetics," they rasped.

"If you take part in this research study, you will have blood samples drawn to see how the drug is absorbed," responded Dorothy. "Individuals in studies are called participants or subjects, not patients, so the distinction between therapy and research remains clear." The jargon soldiers disappeared, one by one, as Dorothy spoke. She walked on.

The gate to the stronghold was closed and barred. "Your own physician encourages you to participate in this important study, which involves gingival biopsies around decidual dentition and limited exposure to ionizing radiation," shrieked the gatekeeper.

"We plan to take samples from the gum tissue around your baby teeth and to take X rays," retorted Dorothy. "Provider endorsement is unduly coercive, and the amount of radiation exposure needs to be compared with the radiation from some other source familiar to the potential subject from everyday life. Now get out of my way. I'm here to deal with the MOP." The gatekeeper shrugged, opened the gate, and flew away.

Dorothy moved on into the great central courtyard of the stronghold. The room echoed with the sound of each step as she walked forward. Her friends were all there, confined behind piles of poorly reproduced, small print documents. Before her, fuming with fury, stood the MOP of Disrespect for Persons, her laptop computer open and operating. "How dare you challenge my consent form language! It came from the study sponsors and was approved by their attorneys!"

"Competent persons are autonomous. They have a right to decide for themselves whether or not they want to take part in a research study. They are entitled to a complete and understandable explanation of the study before they decide whether or not to take part. Without that information, it is impossible for them to give truly informed consent," returned Dorothy.

The MOP gathered herself and glared at Dorothy. The screen of the laptop acquired a

heightened glow. "The possible side effects of this medication include dyspnea, anorexia, ecchymosis, vertigo and orthostatic hypotension," shrieked the MOP.

"This drug sometimes causes shortness of breath, loss of appetite, bruising, dizziness and low blood pressure when standing," replied Dorothy. Sparks shot from the laptop. They ignited the MOP, who disappeared with a shriek in a blaze of flame.

Dorothy collected the smoldering laptop, freed her friends and suggested to the remaining jargon soldiers that they should find work in a crossword puzzle factory. As they all left the stronghold, it began to crumble. By the time IRB was once more in sight, the ruins had vanished and the suns were shining.

News of Dorothy's success spread rapidly, and she was greeted by a cheering crowd of IRBanites at the city gates. She and her friends marched boldly to the Temple of Empirical Knowing. The audience chamber was empty, but the giant screens came to life and flashed "The Wizard is out. Please leave a message." Effie ran next door to the Wizard's office, and reported a dusty, cobwebbed sign that said the Wizard was in a meeting and could not be disturbed.

Dorothy was in no mood for further delay. She dragged two microphones together and created a feedback screech that could be heard throughout the Sapphire City. The Wizard's image appeared on the giant screens.

"WHO DARES TO DISTURB THE MIGHTY WIZARD?"

"It is Dorothy Gale. The MOP of Disrespect for Persons is gone, and so are all her jargon soldiers. Her stronghold is in ruins. Now it is time for you to help me and my friends."

"DID YOU BRING THE LAPTOP? GIVE IT TO ME."

A growing suspicion forced itself into Dorothy's consciousness. "You do have the power to help us, don't you?"

"GIVE ME THE LAPTOP AND THEN WE'LL TALK."

Dorothy was about to answer, but she was distracted by Nono, who was tugging and barking at a curtain in the front corner of the audience chamber. The fabric gave way to reveal an unassuming little man seated in front of a video camera at a mixing console.

"Shoo, doggie! Er, BEGONE DOG!" he said into his microphone.

"Are you the Wizard?" asked Dorothy.

"INDEED I AM THE GREAT AND MIGHTY WIZARD OF IRB!" The video screen images began to break up, as the little man frantically adjusted controls on his console.

"You're nothing but a special effects fraud!" cried Dorothy in despair.

"NOT TRUE. I, TOO, AM FROM ETHICAL RESEARCH. I WAS AN ADMINISTRATOR WHOSE HOT AIR BALLOON WAS BLOWN HERE BY THE WINDS. I RECOGNIZED A NEW OPPORTUNITY FOR MY MANAGEMENT SKILLS AND CHOSE TO SETTLE HERE."

"You can't give my friends beneficence, justice, and respect for persons after all, can you?" Dorothy was by now distraught and angry.

"I AND ALL THE REGULATORS OF THIS LAND CAN TRY, BUT THE PRIMARY RESPONSIBILITY FOR THE DESIGN AND CONDUCT OF ETHICAL RESEARCH

FALLS UPON THE PRINCIPAL INVESTIGATOR."

"So what you're saying is, only I can prevent research abuse," mused Dorothy.

"OH, SO YOU KNOW THE BEAR IN THE RANGER HAT AND BLUE JEANS, TOO?"

"And I suppose I'm also the only one who can get me back home?"

"REMEMBER THE STORMS OF DEMANDS YOU ENCOUNTERED BACK THERE? THE MOPS IN YOUR COUNTRY ARE MORE DIFFICULT TO RECOGNIZE, AND THEY HAVE NOT BEEN VANQUISHED. ARE YOU SURE YOU WANT TO GO HOME?"

"I'm sure", said Dorothy. "I just wish I knew exactly how to do it."

Dorothy's friends and the citizens of IRB clustered around, offering suggestions about large yellow birds and meditation exercises. Nothing worked. Their discussion was interrupted by the arrival of a motorcycle. It was BOP Jane, come to investigate the circumstances of the Disrespect MOP's demise.

"Oh Jane", said Dorothy as she relinquished the MOP's laptop, "I really want to go home, but I don't know how. Are you sure you can't help?"

"Under the circumstances, I think I could reveal some privileged information. The power to return to Ethical Research has always been within you. All you need do is click your heels together three times and say 'There's no place like Ethical Research.' "

"Oh, thank you!" cried Dorothy. She gathered Nono in her arms and said her goodbyes to Effie, Lie-In and Ten, who assured her they would never allow themselves to be victimized by unethical researchers again. She clicked her heels once, twice, and on the third click, she was back in her research office. The phone was ringing, she had 327 new e-mails, and her project administrators had left five memos and fifteen "while you were out" notes on her desk.

"O, Nono!" cried Dorothy. "There's no place like home!" And she conducted ethical research happily ever after.

¹ $P < .0001$, one-tailed ([back](#))

² responsibility for all the locations had been consolidated in the most recent round of "right-sizing" ([back](#))

³ the division chair and Jane assured her that the journey to IRB was a day trip, not requiring overnight accommodations or advance reservations ([back](#))

⁴ This gross overgeneralization of BOP Jane's remarks can only be explained by Dorothy's stress and agitation ([back](#)).

