

## SYSTEM

**Self-Directed Aging Intervention Research**

**Small Study Format**

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[www.AgingIntervention.org/1\\_SmallStudyFormat.pdf](http://www.AgingIntervention.org/1_SmallStudyFormat.pdf)

**Last updated June 23 2019 9:05 am. Constantly improved. Check for updates.**

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**Friendly disclaimer: These are ideas that I use in my own self-directed age management program. It's not my intention to provide specific medical advice but rather to provide others with information to better understand their health. This is not medical advice including diagnosis and treatment. Always seek the advice of a trained health professional for medical advice, diagnosis or treatment.**

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### **PURPOSE**

**The purpose is to implement methods and therapies to slow and ultimately reverse biological aging and age related decline for more years of healthy living. Methods and therapies range from conventional and common sense to experimental pharmaceutical and biological therapies.**

**Biological measurements are taken to evaluate the results and improve.**

**Frequency and dosing are fine tuned, and methods and therapies are carefully combined for best effect.**

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**Short term plan** (since 1999 and into the future about 2-3 years):

Test and refine aging intervention therapy, combinations and dosing program using CURRENTLY AVAILABLE therapies and methods – and measure results -- to gain added years or a decade or two.

Biomarkers/objective measures will be applied to determine the best personal programs.

**Long term plan** starting approx. 2021-2022:

Initiate major program and/or partner with others on development of NEW therapies that will allow us to stay youthful and healthy, and making the world a better place, for as long as we choose – more than a few years or a couple decades.

Includes gene editing, nanotechnology, artificial intelligence, and something that may seem rather visionary and extreme, and even bizarre -- full body transplant with lab-grown bodies (obviously this one is very long term).

And many other innovative advances yet to be conceived.

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**For aging intervention and increasing healthspan start with the fundamentals – USE COMMON SENSE – HAVE REGULAR HEALTH AND DISEASE SCREENINGS**

**I could name a number of prominent people who are deceased – well known individuals as well as members of our own aging intervention community – had they detected diseases and received treatment early would probably still be alive today.**

**To increase healthspan and lifespan, start with the foundation of:**

- **Get early diagnosis and treatment for disease conditions with regular health and disease screenings – regular medical and dental checkups, blood tests, eye screenings, colonoscopy, mammogram and others advised by your doctor.**
- **Great nutrition with reduced calories** (may include some form of **fasting**)
- **Exercise**
- **Mental well-being** – includes stress reduction, adequate sleep, positive thinking, meditation, compassion, forgiveness, and grounding in the present with a vision for the future.

Volumes are written about nutrition, exercise, and mental well-being, and details are beyond the scope of this writeup.

- And dental care, moderate and appropriate amounts of well-designed nutritional supplements, adequate amounts of water (possibly filtered or alkaline), reduce risks, reduce toxicity, personal safety and security, sexuality, spirituality.

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**When I learn of a new aging intervention therapy, some of the many questions I ask include:**

How do we know it works?

Is it safe?

Would we become dependent on it?

Where would it fit in the priority of available therapies?

How do we get it?

What's the cost and is it cost effective?

How to test/evaluate results?

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**A philosophical, and practical question:**

**Are you happy and fulfilled right now on this journey toward longer healthier life? If not, what makes you think you'll be happy after you achieve it?**

**Another one: Why? What will you do with all the extra years, decades, centuries after aging is solved? I suggest considering a purpose, and that might be creating a better world.**

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## **As a Self-Directed Aging Intervention Researcher**

I use what you would call a **Fast Track Proof of Concept Trial, or pilot/beta/small study format in humans**

Conducted individually (N=1) or by a small group of associates, as opposed to a large formal clinical trial.

Keywords: practical, ethical, small, informal, fast track, cautious and low risk with high potential for increasing healthy years

N=1 can render valuable information under the right conditions – **especially if the N = you.**

Everyone's different, and different people experience a wide range of responses to different therapies.

What works in one person may not work in another – and another may experience a negative effect.

Personalized dosing can be important.

How therapies are combined is important. Results can be improved (linearly or exponentially), or therapies can negate one another, or effects can be negative – sometimes very much so.

Uses aging biomarkers and biological/health outcome measures for

- Safety (such as liver, kidney, blood, lipids)
- Efficacy

MD or qualified professional monitored/supervision

Investigational Review Board (IRB) optional

Vital concepts: safety, reducing risk, informed consent and do no harm

Forward thinking, even bold – but not reckless

Bottom line: aging is 100% fatal

Be aware of potential negative consequences of self-diagnosis and independent action.

First do no harm -- be as sure as possible that no harm will come from it. Also remember hardly anything – like driving to your doctor's appointment -- is completely risk-free,

**but aging is 100% fatal.**

### **What to call it:**

Self Directed Aging Intervention Researchers

Aging Solutions, Healthspan, Longevity "Fast Trackers", innovators, visionaries, early adopters, explorers, creators, adventurers, pioneers, citizen-scientists, DIY biohackers, "self selected lab rats"

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## **You Can't Manage What You Don't Measure**

MEASURING RESULTS with biomarkers and other measures is key.

Measure indicators of any harm that may be done.

If you are testing a compound that has had a positive effect in animal studies, measure for those effects in the humans.

**Be cost-effective, but don't scrimp on lab work.**

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## **Testing Pharmaceuticals Purchased Offshore and Elsewhere for Safety and Efficacy**

Counterfeiting products is a huge international problem. It's not confined to jeans, Gucci bags, Barbie dolls and GI Joes -- other items include counterfeit airplane parts, pharmaceuticals and other mission-critical products. Whatever makes money. A doctor once told me about fake Lasix medicine made seriously ill patients even sicker because it had been mixed in a container that had previously been used to mix pesticide, and had traces of the pesticide in the "Lasix".

Appearance and packaging are VERY convincing. I read that a phoney Apple store was opened in China with real looking Apple products.

So I do not automatically trust that offshore suppliers will provide pharmaceuticals that are pure or contain the specified content.

"Canadian" pharmacies are often (probably usually) in Asia, India or elsewhere. It is illegal for a Canadian pharmacy to ship to the US, with or without a prescription. Unless the web address has a ".pharmacy" extension it is not legitimate. The legitimate way to get a Canadian pharmaceutical is to go to Canada and get it from a Canadian doctor, then go to the pharmacy.

Pharmaceuticals can be tested against a generic (known) quality using high-performance liquid chromatography (HPLC) and other methods. Testing labs can be found on Science Exchange [www.scienceexchange.com](http://www.scienceexchange.com). For example, my close circle of associates and I compared dasatinib from a US pharmacy and dasatinib from an offshore pharmacy with a generic (known) quality of dasatinib, which I [acquired from Sigma](#): CAS: 302962-49-8.

[www.sigmaaldrich.com/catalog/buildingblock/product/matrixscientific/mat370173661?lang=en&region=US](http://www.sigmaaldrich.com/catalog/buildingblock/product/matrixscientific/mat370173661?lang=en&region=US)

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## **Testing:**

**Please contact me if you plan to utilize Echelon's services.**

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## Prescriptions May Need a Diagnosis Code

Unfortunately according to medical and other dictionaries *aging* does not fall into the category of a disease. So it is unlikely that the World Health Organization, American ICD-10-CM (diagnosis) and ICD-10-PCS (procedure) medical billing codes, or other major organization will categorize aging as a disease.

**2019 ICD-10-CM Diagnosis Code R54 -- Age-related physical debility** -- as close to getting aging classified as a disease as we'll get – at least for now.

<https://www.icd10data.com/ICD10CM/Codes/R00-R99/R50-R69/R54-/R54>

The above web page reference begins with:

### Age-related physical debility

2016	2017	2018	2019	Billable/Specific Code	Adult Dx (15-124 years)
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- R54 is a billable/specific ICD-10-CM code that can be used to indicate a diagnosis for reimbursement purposes.
- The 2019 edition of ICD-10-CM R54 became effective on October 1, 2018.
- This is the American ICD-10-CM version of R54 - other international versions of ICD-10 R54 may differ.

#### ICD-10-CM Coding Rules

- R54 is applicable to adult patients aged 15 - 124 years inclusive.

#### Applicable To

- Frailty
- Old age
- Senescence
- Senile asthenia
- Senile debility

#### Type 1 Excludes

- age-related cognitive decline ([R41.81](#))
- sarcopenia ([M62.84](#))
- senile psychosis ([F03](#))
- senility NOS ([R41.81](#))

The following code(s) above R54 contain annotation back-references that may be applicable to R54:

- [R00-R99](#)  
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

#### Approximate Synonyms

- Frailty

ICD-10-CM R54 is grouped within Diagnostic Related Group(s) (MS-DRG v36.0):

- [884](#) Organic disturbances and intellectual disability
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Some major pharmacies have an application and qualification process for off label drugs. On one occasion we found a university pharmacy required less formality and was faster.

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**Dose intervals, and skipping intervals can be important depending on the therapy.**

Look to expert input and use your best judgment.

We're on a frontier here.

Unchartered territory.

No man's land.

No woman's land.

Ya pays yer money and ya takes yer chances.

But . . . aging is 100% fatal.

If you are doing doses at different intervals, keep in mind the time after the therapy for it to become effective, and how long it maintains / point at which the effect declines. You will probably only know that by your biomarkers and other objective measures.

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**Feedback Inhibition**

Homeostasis is where a body's mechanisms go into action to achieve a stable, often preset state. When augmenting a substance (often "natural"), you may get a boost in biological measures, and feel great -- at first. You may even want to write a glowing testimonial about the product that's causing it. Then homeostasis begins and the body may compensate by reducing its own production, seeking to achieve the previously set level.

Eventually the body can become dependent, so if the external source is stopped you are now deficient, and dependent on the external source -- very possibly with feelings like weakness, illness, emotional upset or depression, and other really bad things because you're now deficient. It takes a long time to get back to where you originally were -- if ever.

A classic example of this is testosterone and other hormones. Early on (circa 1999) I got into physical trouble with large amounts of testosterone and other mega doses of nutritional supplements and pharmaceuticals.

A user feels good at first, later not good. I would only take testosterone if diagnosed as deficient by a highly qualified endocrinologist -- definitely not one who had minimal training in age management/anti-aging medicine, such as a few courses. Hormone actions are complex. Same goes for any hormone.

If you wrote a testimonial about a product, try to get it removed and the current story posted.

This might be a pretty good case for intermittent use -- of any exogenous substance.

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### **Sometimes things don't go exactly to plan**

We're not lab rats living in a controlled environment. "Life" may well happen – right at a critical time in your self directed age management therapy experiment.

You may get sick, a loved one may die, you may be called to help someone in distress, your work may require unexpected travel, relatives may visit for a few days, and a thousand other things that can throw it off.

For example, I recently had lab work scheduled at an exact time following a therapy. But I had an unusual swelling in a finger, and had picked up about an extra 1.5 pounds of body weight and was concerned this might have an effect on the results, particularly inflammation.

I did the lab work anyway, and noted it in my summary.

And how will flu season affect your experiment? Will you get the flu just at the time of an important followup measurement?

So I do what successful businesspeople, doctors, and others do – make the best possible decisions based on often incomplete information, or dealing with the uncertainties that life throws at you.

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### **Multiple therapies can have synergistic, or multiplicative, or negative effects.**

Safety first, follow doctor's guidance, measure results.

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### **Personalization, Dosing and Combinations**

Different people can experience a wide range of responses to different therapies.

What works in one person may not work in another – and another may experience a negative effect.

And personalized dosing can be important.

Re combinations – it's good to affect multiple aging systems. Sometime therapies with the intended effect or target that don't work individually will work when combined or will work better when combined.

And it would probably be desirable to combine different therapies with different effects or targets on aging systems.

Dosing becomes even more important, as sometimes when combined therapies that worked well with no side effects will now result in side effects. For example, they may compete for the same clearance pathways resulting, in effect, to something like overdoses.

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### **To be determined – the order of therapies**

Example recently discussed and being researched -- first senolytics THEN stem cell therapy. Details soon.

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## **Seasonal Influences**

### **Holiday months -- November and December**

Mistakes by service providers – and our own mistakes -- happen a lot more during the holidays. Delivery people are overwhelmed and shipments get lost or delayed – and that's a big problem if it's a sample on dry ice and the dry ice melts and the sample thaws and is ruined. Delivery people and service providers go to the wrong locations. Labs and medical people are overwhelmed due to large numbers of patients using up their medical insurance deductibles and holiday overload in general.

Lab work may be time sensitive. Many customer support and lab staff are out for the holidays. Or the A-team, and B-team are out and this results in disorganization and samples being stored longer than usual – and increases the potential for mistakes, especially errors in lab values.

For example in Dec. 2017 I sent two blood samples to a lab. One of them either arrived there damaged or was damaged by the lab. Also around the same time a delivery driver missed my sample delivery on his route, which was frozen. Fortunately I had a great relationship with this lab and they called me. Most don't.

I had to waste time and call the UPS supervisor and demand the driver backtrack to the lab and deliver it – otherwise I would have to drive to the main facility myself, pick it up and take it over to the lab. It was delivered later that day.

My preferred shipper is FedEx. This seems to be the case with other major labs.

And since we're humans many of us partake in holiday indulgences, which is outside our normal routine and could make a difference. If we have a therapy and lab work during that time, I suppose it's best to continue the same eating and lifestyle habits until all followup lab and biomarker work is complete. Counterproductive, and is that condition the norm in which to test a therapy?

And how will flu season affect your experiment? Will you get the flu just at the time of an important followup measurement?

Seasonality, or even seasonal affective disorder may affect your results.

At a major academic conference on aging a researcher at a university described the same kind of problem. The lab shut down completely for weeks during the holidays. They were unaware of this when they began working with them, and it resulted in serious problems.

In future it will be extremely unlikely that I will test an important therapy during the holiday months of Nov. and Dec., or during July and Aug.

### **Spring**

Allergies may affect your results. Then there's spring fever.

### **Summer -- vacation months of July and August**



If you are working with scientists, my experience has been that they are on vacation or otherwise unavailable during August, and almost as much in July.

From the above you may conclude that there is no time to do an experiment.  
I suggest dramatic changes will occur under just about any conditions.  
Take action, wisely.

## References

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[www.joshmitteldorf.scienceblog.com/2017/06/06/aging-gets-personal](http://www.joshmitteldorf.scienceblog.com/2017/06/06/aging-gets-personal)

## **This is one in a set of four. See companions to this document:**

1) Background and outlines our mission:

[www.AgingIntervention.org](http://www.AgingIntervention.org)

2) Describes main methods:

[www.agingintervention.org/1\\_SmallStudyFormat.pdf](http://www.agingintervention.org/1_SmallStudyFormat.pdf)

3) Biomarkers and objective measures of results:

[www.agingintervention.org/1\\_BiomarkerPersonalPracticalBasicList.pdf](http://www.agingintervention.org/1_BiomarkerPersonalPracticalBasicList.pdf)

4) Therapies my group of associates and I are evaluating and testing on ourselves:

[www.agingintervention.org/1\\_UpcomingPersonalTherapies.pdf](http://www.agingintervention.org/1_UpcomingPersonalTherapies.pdf)

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\* Please let me know if you review their info or join — [Jadams@grg.org](mailto:Jadams@grg.org) or (949) 922-9786 \*

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