

## **On Barriers to Responsible Scientific Research and How to Remove Them**

### **A Public Comment on NIH Guidelines for Human Stem Cell Research**

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(Received 2009-05-26; accepted 2009-05-26; published 2009-05-26\*)

#### **HIGHLIGHT**

US President Obama ordered NIH to develop a new guideline for removing barriers to responsible scientific research involving human stem cells. But new guideline developed by NIH is far from satisfaction because it has focused just on some parts of a tree but lost the big sight of a forest.

#### **ABSTRACT**

Stem cell research has captured a lot of attentions from scientific communities and general public. Thus, it is not a surprise that US President would choose this research field to begin his action of removing barriers to responsible scientific research. However, without first removing some common barriers in scientific communication and restoring true democracy in scientific research, any responsible scientific research in stem cell field is hard to come. Using recent events happened around controversies on iPSCs (induced pluripotent stem cells) for example; this public comment identified the most important factors contributing to the degeneration of morality in science. It also proposed some measures for removing barriers to responsible scientific research. A revolution in scientific publishing is called for the return of true Enlightenment.

#### **KEY WORDS**

Science, Research, Funding, Responsible, Stem cell, Barrier, Openness, Transparency, Revolution, Publishing, Communication, Dogma, Misconduct, Guideline, Law, Regulation, Truth, Enlightenment

On March 9, 2009 US President Obama issued an Executive Order (13505) - Removing barriers to responsible scientific research [1]. While it is natural for people to focus on a named application of this order – research involving human stem cells, it would be a pity if we should lose sight of the grand goal of this Executive Order - removing barriers to responsible scientific research – in its broad scope.

So before I deal with specific issues on human stem cell research as outlined in the NIH's Guideline [2] developed in response to the President's Executive

Order, I wish to address the grand goal of the Executive Order.

First I wish to define the meaning of “responsible scientific research”. By convention, science is “knowledge covering general truths” [3]. So if the science we are taught is about the truths then it should be naturally responsible. Then, why would it require a President to issue an Executive Order to remove the barriers to responsible scientific research?

Apparently, there are some “scientific” researches which are irresponsible and/or there are some barriers which have prevented irresponsible “science” from being removed and/or blocked responsible science from coming in.

Secondly, I wish to identify some common barriers to responsible scientific research before I go into details of some irresponsible scientific research, especially in the field of stem cell research. I believe that, without removing these common barriers, no specific scientific discipline can become really responsible.

There are many common barriers to responsible scientific research. But the most significant and thus extremely harmful include:

1. Forces against transparency and openness in scientific communication;
2. Forces against democracy and objectivity in scientific evaluation;
3. Forces against regulation and discipline of scientific conduct.

Scientific research is a non-stop inquiry about nature and its laws of operation. Scientific knowledge is enriched through absorbing new discoveries and improves by discarding dogmas. This enrichment and improvement process requires open communications among scientists and transparency between scientific community and general public. Thus, openness and transparency in scientific communication should be mandatory for responsible scientific research. However, are today’s scientific communication systems really open and transparent [4]? Why most scientific journals still heavily rely on secret peer-review systems that have been proven largely ineffective against irresponsible scientific research and mostly responsible for protection of plenty of misinformation and even some misconduct in scientific research[5-8]? Why an open review system cannot be widely implemented in scientific publishing [9] or a few open-review journals not popular among scientific communities [10]? Why immunity should be given to journals which have published flawed and even fraud “discoveries” repeatedly [11]? Why are those fraud-publishing journals even allowed to keep their problematic handling of irresponsible research as some secrets [12-14]? There have been some irresponsible scientists being punished with the retractions of their flawed and even fraud “discoveries” [15]. But have any repeatedly irresponsible journals been really punished for its truly irresponsible behaviors in scientific publishing [16-19]? No! As a matter

of fact, those journals publishing “hot” but flawed research often received more citations and thus higher impact factors because retracted publication resulting from irresponsible research often collects more citations than comparable responsible researches and negative citations are significant contributors to presumably positive impact factors [20-23]. Being aware of many and often reported flaws in the impact factors [24-28], why would some journals still want to keep playing the impact factor game? How can it be that the flawed and even fraudulent impact factor is allowed to dominate the evaluation of scientific publishing and pollute the candid and authentic spirit of scientific research [29]?

When scientific communication is not truly open and evaluation of science is not made in a genuinely transparent way, democracy and objectivity in scientific evaluation is hard to guarantee [30, 31]. As a matter of fact, subjectivity and even dictatorship in scientific evaluation happen all the time [32, 33]. Many people have complained about the interference of politics on science. But the major resistance to scientific advancement comes from the scientific community [34-37]. It is the strong protection of dogmas by some scientific authorities that have stalled the advancement of science to the most degree [38-42] and contributed to the blooming of most irresponsible “scientific” research [13, 43-47].

It is actually these “scientific” heavy-weights who are the strongest opponents of any regulation and discipline on scientific research [48]. Their fight for the “freedom” in scientific research is in essence an effort for maintaining their “immunity” against any regulation and discipline on their irresponsibility in scientific research [49, 50].

Thus, without removing these major common barriers, true responsible scientific research cannot come or may not be maintained even if it comes.

Now, let me address some specific presentations of irresponsible scientific research and how the above common barriers have been used against responsible science in the stem cell research.

Recently, a huge effort has been made to promote iPSCs – induced pluripotent stem cells [51]. The discovery of iPSCs have been described as directly reprogramming terminally differentiated adult cells into pluripotent stem cells that are indistinguishable from embryonic stem cells (ESCs) [52]. This technique has been heralded as having the real

potential for easily and quickly developing patient-specific therapeutic stem cells that are not only safe (cancer-free) but also ethical (not destroying any embryos). These descriptions not only excited the stem cell research community and raised hope in general public but also pleased the previous White House administration and resulted in major shift in research funding.

However, are all the above claims made for iPSCs true?

Some criticisms have been expressed from the very beginning to challenge all the major claims made in the publications describing the discoveries on iPSCs and/or promoting the applications of iPSCs [53]. These criticisms include:

1. A challenge on the direct reprogramming claim for inducing pluripotent stem cells from differentiated cells and a proposal of alternative view that iPSCs are most likely incorrectly programmed stem cells from existing stem cells;
2. A challenge to the “indistinguishable” claim made for iPSCs as compared with ESCs and a conclusion that iPSCs are not only different from ESCs but also different from normal adult stem cells (ASCs);
3. A challenge to many “cancer-free” claims made for different generations of iPSCs and a conclusion that iPSCs are man-made cancer cells;
4. A detailed hypothesis on how iPS technique turns normal cells into cancer cells and a challenge for iPSC research to prove their cancer-free claims and disprove the iPSC oncogenesis hypothesis;
5. A warning against the potential abuse of iPSCs into biological weapons that could result in permanent genetic changes in human population and even serve as sub-population-specific biological bombs.

These criticisms were all initially submitted to various relevant journals which have published the iPSC papers being criticized. However, even until today, none of these journals have accepted any of the above criticisms for publication [53].

All of the above criticisms were later published in double-open (open access and open review) scientific journals and sent to the corresponding authors of the criticized iPSC publications for rebuttal [53]. However, none of the corresponding authors have submitted any response to be

published as a rebuttal. As a matter of fact, most of the corresponding authors even did not respond.

Besides the formal publications of the above criticisms in double-open scientific journals, a peer-reviewed Review on iPSCs was also published in a well-established and well-respected stem cell journal [54]. That publication has been heavily downloaded (ranked as number 1 or 2 most downloaded publication in that journal since its publication) but no citation has been found for it in any major publications on iPSC research, despite the fact that some of the views PUBLISHED in that review have been reflected in some later “fresh looks” on iPSCs [55].

Many comments disclosing those alternative views on iPSCs have been posted on the public comment windows/blog sites of some “top” journals [56, 57]. However, often these comments were removed by the journals without justifiable reasons or even without giving any reason [58]. Some of these comments publicly invited all iPSC researchers to evaluate the alternative views on iPSCs and engage in constructive debate on some contention points. However, no iPSC researcher (in real name) has responded to these public invitations. Instead, some people (groups) under pseudo-names have posted even some name-calling and personal attacks in the highly-respected professional top journals [59]. Those defamatory comments were kept by a journal despite of repeated protests while this journal repeatedly deleted scientific criticisms despite repeated protests [59].

Now, many of the claims made for iPSCs have been solidly proven as untrue. But no journal publishing those high-profile iPSC papers has issued any retraction on those untrue claims, not to say paid appropriate attribute to the critics. A prominent iPSC researcher who has played a major role in suppressing criticisms on iPSCs now states in *Nature* that those criticisms are just unpublished [60] despite the fact that he was even given copies of the PUBLISHED criticisms [61-64] and a peer-reviewed critical review on iPSCs has been published in a mainstream stem cell journal [54].

So, while some unknowledgeable scientists should be blamed for their initial misunderstandings of some scientific issues [54, 65, 66], the biased publishing industry for “scientific” communication should take an even large share of punishment for their deliberate promotion of some misunderstandings in science [49, 51, 52, 67, 68].

Scientific research is about seeking truth. However, truth is not easy to be understood in many times. Thus, an open communication for exchanging different views is essential for scrutinizing more truthful from somehow untruthful observations and interpretations in scientific research and publication [10]. Frankly, I think many stem cell researchers are not even sure what a stem cell should be [69] because the currently widely accepted definition on stem cell is flawed and indefinite [70]. As a matter of fact, the whole cell biology has been established on a fundamental misunderstanding of cell life – a cell division view instead of a cell reproduction view [71]. This fundamental mistake has doomed cell research including stem cell research into some paradoxical state [72] which should have been overcome a long time ago if truthful revelation of cell life had been allowed into the mainstream [73].

By suppressing alternative views and even trash solid critics [38, 40-42, 74, 75], a biased publishing industry [4, 76-78] has advanced some pseudo-science to the largest extent in the history of human civilization [79, 80]. Thus, this unscientific and irresponsible publishing practice has directly or indirectly promoted irresponsible “scientific” research and is the most severe barrier to responsible scientific research [81, 82].

Therefore, we need to overcome this most significant and also most imminent barrier first if we wish to usher in an era of responsible scientific research. Fortunately, a true revolution in scientific publishing has already begun a decade ago [10, 83-85]. But more public support is needed for this genuine revolution. Right now this genuine revolution in scientific publishing is largely a single man’s efforts [85], but it is hoped that the whole scientific community will be united as one responsible scientific research unit with open communication and transparent evaluation on scientific discoveries [83, 84]. In that way any dishonesty and unethical behaviors would be easily exposed to public and any flawed views would be quickly subjected to criticisms before they are cast into any dogma.

In comparing with the above broad scope view of “removing barriers to responsible scientific research” as ordered the by the US President, NIH’s draft Guidelines for human stem cell research [2] is apparently far from satisfaction. This guideline focused on a tree but lost the sight of a forest. It essentially has responded to a political requirement of defining the so-called “ethical” stem cells for research but missed a basic requirement for

defining the essential features of responsible scientific research, especially involving human stem cells.

Thus, major revisions should be done to address the above significant deficiencies in the NIH Guidelines for human stem cell research. Instead of focusing only on defining what stem cells are “ethical” for research, the Guidelines should be expanded to include provisions on how to define responsible scientific research in its broad as well as narrow senses and articulate some general and specific measures for implementing responsible scientific research.

Some suggested measures are:

1. All authors especially those designated as “corresponding” authors, should be required to provide response to scientific criticism and/or ethical question on their research especially on their PUBLISHED research;
2. All journals which has published the research being criticized should be required to PUBLISH scientific criticism and/or ethical question on their PUBLICATIONS (online only and/or in print);
3. All invalid conclusions and/or untruthful statement of any PUBLISHED research should be PUBLICLY confronted with a truthful statement as contained in a retraction or correction, regardless of whether or not a misconduct is involved in the original research;
4. Before a fully-open and totally transparent scientific publishing system is established all journals still insisting on secret peer review should be required to submit at least the review comments they received for the flawed publication so that some real lessons can be learnt from the mistakes previously made;
5. Any person or organization persisting in irresponsible behavior towards scientific criticism should be barred from receiving any support of PUBLIC TAXPAYERS’ money;
6. All parties involved in the suppression of scientific criticism should be subject to criticism or condemnation according to some rules and regulations TO BE ESTABLISHED.

Besides these major revisions covering the general aspects of stem cell or any responsible scientific research, the NIH Guideline should also add more iPS cell research as ineligible for public funding. These amended ineligible iPS research directions should include (continuing with the already identified on section III):

C. Research in which a human embryo or embryos are destroyed discarded or knowingly subject to risk of injury or death greater than that normally seen in natural reproduction.

D. Research in which a known oncogenic factor (including oncogene, oncoprotein and onco-RNA) was included in the generation of pluripotent stem cells that are cancerous by nature.

In addition, the written informed consent obtained from a donor of source cells for making iPS cells should include information that the donated cells may be changed genetically and/or epigenetically to even possess some harmful effects [86]. Similarly, the informed consent given to a recipient of the iPS cell treatment should include information regarding the genetic and/or epigenetic changes that have been made intentionally or produced unexpected from some unknown processes. The informed consent should not contain unverified information such as stating that the iPS cells are genetically identical to the recipient and thus are at no risk of being rejected by the recipient's immune system unless there is an absolute proof for such claims.

Now, having amended some detailed regulations on iPS cell research and clinical applications, I wish to come back to the general rules and regulations TO BE ESTABLISHED. Ideally, this should be a high priority for the NIH or other more appropriate governmental agencies to look into this matter first. This is because, without such rules and regulations controlling responsible scientific research, no responsible scientific research can be really established or maintained.

When faced with a legal complaint of "4D" actions [59] which include

- (a) Repeated DECEPTION in science with rejections of all submissions from Plaintiff 1 and ignoring all publications from Plaintiff 2 against untruthful claims and erroneous descriptions appeared in Defendants' publications;
- (b) Repeated DEFAMATION to Plaintiff 1 even with name-calling, character trashing, and direct personal attacking and to Plaintiff 2 with image-degradation and

reputation attacks aimed at destroying its moral integrity and scientific value;

- (c) Repeated DISCRIMINATION against a Plaintiff 1 by selectively deleting statements made by the Plaintiff 1 and against Plaintiff 2 by intentionally ignoring pioneering publications appeared in Plaintiff 2's scientific journals.
- (d) Repeated DISRUPTION on normal scientific communication by deleting statements published by Plaintiff 1 and his supporters, removing their user accounts, preventing their access to the Defendants' communication systems declared to open to public and even locking a blog system completely to block normal flow of scientific exchanges,

the legal team of *Nature*/Macmillan has even requested the case be dismissed by a court [87]. One reason stated in the motion for dismissal is: "deception in science", "discrimination by selectively deleting statements" and "disruption of normal scientific communication" are not "cognizable under the common law".

Thus, without developing the much needed rules and regulations for responsible scientific research, irresponsible research will be continued and flawed information will still be maintained in scientific publications especially those in the mainstream. For examples, *Cell* has maintained an invalid conclusion that "Takahashi and Yamanaka (2006) have successfully reprogrammed terminally differentiated cells to a pluripotent state" [88] despite the publication of many solid criticisms [54, 61-63, 89-91] and even an admission by Yamanaka that "We have never claimed that we generated iPS cells from terminally differentiated cells" [63]. *Nature* has published so many papers claiming iPS cells are "indistinguishable" from embryonic stem cells (ESCs) [92, 93] but, by contrast, has firmly refused to publish any solid criticism disputing this claim [39]. Nevertheless, knowing the existence of criticisms published against this invalid claim, it still published a false statement by Jaenisch that those observations on the distinctions between iPS cells and ESCs are "just unpublished" [60]. *Science* has rejected all of my Technical Comments on its publication on iPS cells [94, 95] and even ignored repeated requests for investigating some data problems revealed in some of its publications on iPS cells [96].

Thus, when the "CNS" of scientific publishing enterprise has become rotten to such a degree that even some truthful revelations on scientific

research are not allowed and some outright lies can be firmly maintained [5], how could we expect responsible scientific research to flourish in the mainstream [29]? As a matter of fact, many “peripheral” journals just followed the bad examples of the most “top” journals in judging the “trends” of science and pushing the “right” buttons [76]. For example, some concealments of conflict of interest by some iPS cell researchers were exposed recently. However, none of the journals receiving such revelation would even be willing to publish Letters/Correspondence asking for clarifications/corrections. *PNAS* had chosen to rather believe a “satisfactory response” from its prominent author than give a benefit of doubt to a courageous whistleblower [97]. Only after facing some strong protests (electronically in front of many powerful figures in science) that *PNAS* finally agreed to ask the author to make some correction. But it still refuses to disclose even the directly related content of the originally “satisfactory response” that led to the rejection of the submitted exposure Letter and still keeps its rejection decision citing “Letters may not include requests to cite the letter writer's work, accusations of misconduct, or personal comments to an author”[97].

Even worse than these refusals to publishing truth-revealing information, some journals have engaged in public condemnation of responsible scientists [59]. In response to the publications of criticisms to some flaws in iPS cell publications and right after rejecting a comprehensive review on iPS cell research [89] which revealed some data problems [95] in Yamanaka's just published *Science* paper (on line version only then) [98], an Editorial in *Nature* states “The criticism of Yamanaka's article came from an anonymous source who seemed bent on a personal attack”[99]. In a strictly moderated comment window for a News article [100] following this Editorial, the responsible scientist was even identified as a “madman”, “just plain neurotic”, and “a nuisance” in a series comments allowed by *Nature* [59]. These name-calling personal attacks were well kept by *Nature* while many truth-revealing scientific comments were repeatedly removed by *Nature*, often without any reason despite repeated protests and requests for a reason [59]. Eventually, the publishing executive editor even posted comments under her real name to denounce scientific criticisms as a result of single spammer and even engaged in public discussion with others who called this responsible scientist as “pest” [59]. These activities aimed at destroying the credibility and reputation of a

scientifically insightful and ethically responsible scientist continued over a year until a legal lawsuit was filed. Then amazingly, all the comments previously PUBLISHED under some *Nature News* were COMPLETELY deleted. However, *Nature* has issued no apology to the reputation-damaged responsible scientist and even continued in rejecting his truth-revealing submissions. The legal team for *Nature/Macmillan* now state that “none of the statements complained ... constitute publications which are defamatory *per se* and, more amazingly, “the statements complained of ... are not capable of being proved true or false” [87].

Thus, the irresponsible scientific research as revealed from some stem cell research represents just a tiny tip of a huge iceberg which has maintained its coolness since the loss of last Enlightenment [7, 101, 102]. Many career scientists are now hijacked onto some impact factor-searching band wagons, their primary goals are thus no longer searching truth but seeking recognition [29, 103-106]. Truth can be found only in one way – telling nothing but the truth – the very objective observations and logical interpretations on the observations [107-112]. However, recognition can be found in various ways including faking data and fabricating discovery [113-116]. Unfortunately, many successful and thus powerful “scientists” nowadays are just those politically seasoned “professionals” or “figure heads” as called by a “stranger” Russian mathematician who single-handedly resolved a very difficult math conjecture [117] but refused to re-publishing his finding in any peer-reviewed top journal [118].

We definitely need a very specific guideline on how to carry out responsible scientific research involving human stem cells. However, we urgently need a clear general guideline on how to perform responsible scientific research in all scientific disciplines.

Science has no border limits. So is, unfortunately, the damage of irresponsible scientific research. While many scientific awards are truly international in scope [119], punishment on scientific irresponsibility often varies location by location [44, 120, 121]. Thus, for promoting responsible scientific research that is beneficial to all human beings, we also need to establish some common laws, regulations and rules that are implementable throughout the whole world. Internet communication has tied together almost every corner of the whole planet as one global scientific community. We should not allow sectional statutes

to block justice from serving to anyone hiding anywhere.

To achieve that grand goal, we may need to have the heads of all nations to come to a consensus conclusion that, for the common benefits of humanity and civilization, we need a revolution in scientific research and publishing [83, 84].

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\* The main body (without references) was submitted on May 26, 2009 to NIH website for collecting public comment on its Guidelines for human stem cell research.