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August 18, 2009

BY ELECTRONIC MAIL TO: ipregs@cirm.ca.gov

C. Scott Tocher, Counsel
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107

RE: Comments on Proposed Intellectual Property Regulations for Non-Profit and For-Profit Grantees (http://cirm.ca.gov/sites/default/files/consolidated.regulations.round_.3.final_.pdf)

Dear Mr. Tocher,

The University of California appreciates the opportunity to provide comments on the August 3, 2009, revisions to the proposed Intellectual Property Regulations for Non-Profit and For-Profit Grantees by the California Institute for Regenerative Medicine (CIRM). We note that a number of important and helpful revisions were made in this latest version. However, as expressed in our previous letters, we remain very concerned that the new regulation continues to incorporate fundamental changes from the existing regulations that we consider to be quite problematic and that are likely to make CIRM funds less attractive to researchers than other funding sources. The areas of particular concern to us continue to be the reach to past and future research and the expansion to the entire spectrum of research results, including even day-to-day data. We have discussed these concerns extensively in our responses to the previous two versions of these proposed regulations.

The following are our specific comments, presented in the order in which they appear in the proposed new regulation:

100601 (a): The Authorized Organizational Official does not personally assume the obligations. For clarity and accuracy, we would suggest: *"...and to obligate the Grantee to assume the obligations..."*

100601 (c):

- The latest revisions expand the scope of CIRM-Funded Inventions dramatically and inappropriately; we assume that this was not what was intended and would suggest simply

deleting the last ten words of the definition ("...or within 12 months of the close of the Grant"). This language would include inventions that are reduced to practice in the 12 month period after the end of the Grant, even if they were not conceived in the performance of the Grant, i.e., inventions that were neither conceived nor reduced to practice with CIRM funding. Without the above edit, CIRM would be imposing all of the obligations of these regulations on inventions that were conceived and reduced to practice *entirely without CIRM funding*. This is grossly inequitable, and we must assume it is not what CIRM intended, especially as we made a similar observation with the December 19, 2008 version of the proposed regulations which was addressed in the July 17, 2009 version.

- We are also gravely concerned about the continued impact on researchers who do not have the benefit of receiving CIRM funds. Unlike CIRM-funded researchers, these unrelated researchers are not even aware of the impact on their research results, and do not have the opportunity to decline the CIRM funds if they choose not to incur the CIRM obligations. To address this, we would recommend revising criteria (1) to read: *"...and reduced to practice by a Grantee, Grantee Personnel and/or its Collaborator in the performance of a CIRM-Funded Project or Activity or within 12 months of the close of the Grant."* (Note also the deletion of the comma following Activity.)
- Please refer to our previous comments (attached for your easy reference) for our concerns and suggestions on straying from patent law in defining inventions (by use of the phrase "whether patentable or not") and the reach to prior conceptions (reduced to practice with CIRM funding) and future reductions to practice (conceived with CIRM funding) made by CIRM funded researchers.

100601(p): The definition of Invention should not diverge from patent law. We continue to recommend simply saying: *"Any invention or discovery that is or may be patentable or otherwise protectable under Title 35 U.S.C."*

100602(c):

- In our response to the July 17 revisions to these proposed regulations, we expressed concern with requirement to report patent applications "disclosing" CIRM-Funded Inventions, since it is likely to be impossible to identify unrelated patent inventions that simply disclose a CIRM-Funded Invention (probably as part of the specification). The introduction of a "citation to a publication concerning" any CIRM-Funded Invention does not solve this problem since the drafter of a future unrelated patent (usually outside counsel), in citing publications in the scientific field, will have no way of knowing that the publication "concerns" a CIRM-Funded Invention. It is not clear to us why CIRM would want to broaden reporting beyond patents "claiming" CIRM-Funded Inventions, but perhaps a more reasonable approach would be to include patents that cite CIRM-Funded Inventions. This would still be administratively burdensome, but is at least theoretically possible.
- We note that the use of "disclosed" still occurs in item (3), and see no reason why CIRM would need to know the funding sources for a CIRM-Funded Invention that is simply disclosed as background in a specification for a different patent, especially if the CIRM-Funded Invention was never patented or commercialized. In addition, as discussed above,

it will likely be impossible to identify patent applications that simply "disclose" a CIRM-Funded Invention.

- In our response to the July 17 revisions, we suggested that research funding be expressly excluded from the revenue considered for item (5), since it does not seem to be CIRM's intention to include such funds. We note that in this latest revision, research funds are now excluded from the defined term "Licensing Revenue" and would suggest that either the defined term be used in item (5), or that a specific carve-out be made for subsequent research funding.
- All of the above concerns are magnified when one considers the third party reporting requirements. It is appropriate for third parties to report patents "claiming" CIRM-Funded Inventions and licenses and revenue associated with such patents. But it is entirely inappropriate to require third parties to report any of their own patents that simply refer to CIRM-Funded Inventions as background information, or to disclose funding sources for CIRM-Funded Inventions that are merely "disclosed" in a patent application (e.g., as background information), but which will not be commercialized.
- Finally, it is inappropriate and unnecessary to require Grantees to have agreements with their own personnel concerning the reporting requirements of subdivision (c). Since the Grantee is already obligated to provide these reports, this is an unnecessary administrative step, especially as Grantee Personnel are not generally considered "third parties".

100606(a): In our response to the July 17 revisions, we expressed concern with a requirement to commercialize CIRM-Funded Technology, since data, research results, etc., are very rarely of commercial interest and it would be a poor use of limited resources to attempt to do so. The introduction of "otherwise bring to practical application" does not solve this problem, as there is rarely a "practical" application for data and the vast majority of "research results." Yet the penalty for not doing so ourselves is to attempt to convince a third party to commercialize or bring to practical application something for which such effort is not warranted. As we suggested last time, we strongly recommend that this requirement be limited to just those CIRM-Funded Technologies that actually do lend themselves to commercialization - perhaps to *"CIRM-Funded Technologies with potentially useful application in the treatment and diagnosis of disease"*, or *"with potentially useful commercial application"*.

100606(b): As discussed in our response to the July 17 revisions and above we noted that the vast majority of CIRM-Funded Technology (i.e., day-to-day data and research results) is not of broad interest – commercial or otherwise. Yet, as written, this provision requires a Grantee to either expend the resources attempting to negotiate non-exclusive licenses, or make the effort to push everything into the public domain. We presume that normal academic practice of scientific presentation and publication is sufficient to address this requirement.

100606(h): As discussed in our response to the July 17 revisions, we think it is inappropriate, and would be distasteful to our licensees, to have to report *all* breaches to CIRM, even those that are promptly resolved, and recommend that this requirement be scaled back as described in our earlier letter.

100607(f),(g): There is a second instance of "a Drug", on line 2 of each section, that should be "the Drug."

100610: Please refer to our earlier comments for a discussion of our serious concerns with potentially being compelled to exclusively license fundamental research results, such as data.

Again, we appreciate the opportunity to comment on the proposed intellectual property regulations. If you have any questions about any of our comments, please don't hesitate to contact us.

Sincerely,

William T. Tucker
Executive Director
Research Administration and
Technology Transfer

cc: Vice President Beckwith
Executive Director Auriti
Director Streitz

Attachment to Aug. 18, 2009 letter

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July 31, 2009

BY ELECTRONIC MAIL TO: ipregs@cirm.ca.gov

C. Scott Tocher, Counsel
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107

RE: Comments on Proposed Intellectual Property Regulations for Non-Profit and For-Profit Grantees

Dear Mr. Tocher,

The University of California appreciates the opportunity to provide comments on the proposed adoption of Intellectual Property Regulations for Non-Profit and For-Profit Grantees by the California Institute for Regenerative Medicine (CIRM). We continue to be concerned that the proposed regulation does much more than simply consolidate the existing regulations, in many cases significantly adding to the administrative burden of grantees and their licensees. There are increasingly alternate funding sources available, including the federal government now that federal restrictions have been relaxed. Absent a compelling reason to do otherwise, researchers and research institutions will seek funds that are less burdensome to manage and industry will be more likely to invest in inventions that carry fewer strings.

Reach to past and future, non-CIRM funded research. One of our most serious and overarching concerns continues to be the new reach to past and future research that is not funded by CIRM. The proposed regulations introduced a new reach to inventions that were wholly conceived in previous research, almost certainly not funded by CIRM; because of the inequity in reaching to a novel idea that was developed prior to the current research, and the difficulty in avoiding conflicting obligations, UC does not give its sponsors rights to prior conceptions. The proposed regulations also reach to future reductions to practice, also likely made under third-party funding (though we greatly appreciate the fact that this future reach is now limited to a one-year window); because the CIRM requirements do conflict with the requirements of many other sponsors, a grantee may need to severely limit a researcher's potential future funding sources for a full year after the completion of the CIRM-funded project. Needless to say, academic institutions are very reluctant to place such constraints on their researchers, particularly their young researchers such as students and post-docs, for whom this work represents nearly their entire body of research.

Perhaps the most troubling impact of this new language is that the regulations could now impact researchers who have never benefitted from CIRM funding. The current language of the regulations would sweep in prior conceptions made by *any* grantee researcher, and would similarly reach forward to future reductions to practice made by *any* grantee researcher. This goes against the strong academic culture (and in UC's case, documented fundamental academic Principle) of informed participation, under which every researcher has the right and responsibility to know how the terms of a research agreement will affect him/her, AND has the ability to "opt out" by declining the funding. Under the proposed regulations, that is no longer possible. For example, a researcher funded entirely by non-CIRM funds may become aware of a conception through the publication of a CIRM-funded colleague and subsequently reduce that conception to practice. Through the proposed regulations, all the CIRM obligations and requirements now attach to the efforts of this subsequent researcher, without his/her knowledge or consent and without him/her having ever received CIRM funding. [Note that researchers at other institutions who read the same publication have more freedom to proceed without constraints than do a grantee's own researchers.] We can't overstate how important an issue this is to UC. We have made some specific suggestions below to address this issue, and would ask that CIRM give them very serious consideration.

Expansion beyond patentable inventions. Another major concern continues to be the expansion beyond patentable inventions to data, results, materials, know-how, etc. The vast majority of day-to-day results, data, etc. are not particularly useful or of substantial interest to either the scientific or commercial communities. Rather, it is the significant findings, the compilations of data, those materials that have research uses and the occasional invention that are of interest. There is not sufficient benefit to CIRM to warrant the administrative burden involved in reporting and tracking the day-to-day detritus of a research project. Licensing programs of research institutions generally limit themselves to patentable inventions for good reason. Note that the expansion beyond patentable inventions also greatly complicates the issues associated with the past and future reach described above, perhaps to the point of being completely unmanageable. For patentable inventions, we know when there has been a conception or reduction to practice, but it's not even clear what these concepts mean outside a patent law context. For example, when is data reduced to practice? We have included some suggestions to help address this in the comments below.

The following are our specific comments, presented in the order in which they appear in the proposed new regulation:

100601 (a): The Authorized Organizational Official does not personally assume the obligations. For clarity and accuracy, we would suggest: *"...and to obligate the Grantee to assume the obligations..."*

100601 (b-new): (Note the lettering of paragraphs in 100601 is off.) The definition of Budget Period is somewhat unclear and might be helped by a relevant reference. One possibility would be: *"...for budgetary funding and reporting purposes as specified in the relevant NGA."*

100601 (b-old):

- The concept of an unpatentable invention is decidedly unclear; whatever this is, it almost certainly falls under the broad definition of CIRM-Funded Technology. We would suggest that the definition of CIRM-Funded Invention be limited to an Invention *"that is or may be*

patentable." Further, we suggest that this clarification be made in the definition of Invention, rather than here (see below).

- As mentioned above, the reach to prior conceptions and future reductions to practice places serious limitations on our researchers and creates tremendous administrative burdens as we strive to avoid conflicting obligations. We do not permit other sponsors a similar forward or backward reach (other than the federal government), as it is inequitable and very difficult to administer. We would ask that this definition be limited to inventions that are conceived AND reduced to practice in the performance of a Currently Active Grant.
- If, however, CIRM feels it must place itself in a position that is more privileged than other sponsors, we MUST ask that this provision not impact researchers who neither have the benefit of receiving CIRM funds, nor the opportunity to decline because of the impact on their research. Please see suggested language below.
- We would request that the phrase *"during the performance"* (2 places) be replaced with *"in the performance"* to be clear that the invention is made under the Grant and not just concurrent with the grant (even perhaps by unrelated Grantee researchers).
- Similarly, and also to parallel the language used in condition (1), we suggest that condition (2) be modified as follows: *"...is reduced to practice by a Grantee and/or its Collaborator(s)* ~~*during*~~ *in the performance of a Currently Active Grant."*
- Following on all of the above comments, we would suggest that the definition for CIRM-Funded Invention be modified to read as follows:

  "An Invention [separately defined as one that is or may be patentable] *that arises from CIRM-Funded Research and either (1) is conceived by Grantee Personnel and/or personnel of Collaborator(s) in the performance of a Currently Active Grant and/or reduced to practice by Grantee Personnel and/or personnel of Collaborator(s) in the performance of a Currently Active Grant or within 12 months of the close of the Grant, or (2) is reduced to practice by Grantee Personnel and/or personnel of Collaborator(s) in the performance of a Currently Active Grant."*

100601(d): As with the discussion above, we would ask that CIRM-Funded Technology be limited to that which is created in the performance of a Grant. We feel it is entirely inappropriate for CIRM to impose any requirements on data, results, etc. that are created outside of CIRM funding – in an academic environment, this is a far more egregious reach than with inventions. And since CIRM-Funded Technology does not include inventions (which would fall under the above definition), we would recommend not using concepts of patent law such as conception or reduction to practice, as that creates confusion. As with our first set of comments, we would recommend a definition such as the following: *"Data, materials, research results or know-how that are first generated in the performance of a Currently Active Grant and paid for in whole or in part with CIRM funds."*

100601(e): We previously expressed concern that the definition of Collaborator in the first version of the proposed regulations would reach to researchers who are not performing within the scope of work of any CIRM Grant, but are simply doing related work (perhaps in conjunction with a separate Grantee project funded by a third party). We recognize that most instances of the term "Collaborator" in the proposed regulations are in a context that makes the CIRM connection clear, but this not true for all instances. For simplicity, we had suggested that the concept of participation in a CIRM Grant be included in the definition of Collaborator, which would then carry throughout. For this reason, and because we feel it is more clear, we would support the Option B definition. However, we would suggest

the following change, as we believe the issue is not so much ownership as creation of the CIRM-Funded Invention or CIRM-Funded Technology: *"...(ii) who ~~obtains ownership rights to~~ creates CIRM-Funded Inventions or CIRM-Funded Technology."*

100601(f)(ii): The definition of Currently Active Grant should be tied not only to funding, but also to a scope of work for purposes of this regulation. The proposed definition would have the IP provisions apply even if a project is completed (if there are still unreturned funds), which makes no sense if there is no ongoing research. In this situation, there is certainly a financial issue to be resolved, but it is not appropriate to continue to consider the Grant active for IP purposes.

100601(o): The definition of Invention should not diverge from patent law (see also above discussion of conceived OR reduced to practice and "unpatentable" inventions). We would recommend simply saying: *"Any invention or discovery that is or may be patentable or otherwise protectable under Title 35 U.S.C."*

100601(q): The statutory rights under patent law (make, use, sell, etc.) do not include "develop." We recommend that "develop" be deleted.

100601(v): We would recommend Option B, as it more accurately reflects the nature of a non-exclusive license.

100601(y): The ninth word should be "that" rather than "than".

100601(aa): For clarity and consistency, we would recommend using a defined term rather than the undefined "project or activity." One thought would be: *"The amount of time over which CIRM funds a Grant."*

100602(a): As we have commented before, the requirement to disclose the complete range of CIRM-Funded Technology is unmanageable. To comply, researchers would have to disclose the results and data of their research to an administrative office on a daily basis, most of which is not of interest from an intellectual property or commercialization perspective. This also represents time that the researcher(s) could have spent conducting their research. As discussed earlier, we would much rather see a return to the scope of the existing regulations which are focused on patentable inventions. This scope is clear, and it encompasses the vast majority of commercially interesting research results. However, if CIRM feels that it absolutely must address other forms of research results, we would ask that the disclosure requirement be limited to more a manageable and relevant range of research results – perhaps to *"CIRM-Funded Technologies with potentially useful application in the treatment and diagnosis of disease"*, or *"...with potentially useful commercial application"*.

We also note that the use of the vaguely defined term Collaborators in this section does not carry with it a context limiting the term to those who are collaborating within the scope of a CIRM-funded project. To address this, we recommend that the Option B definition of Collaborator be used, modified as above.

100602(c):

- We strongly recommend removing "disclosing" from the phrase "patent applications disclosing or claiming" CIRM-Funded Technology and CIRM-Funded Inventions throughout (four occurrences). The patent applications to which CIRM obligations apply are only those

which actually "claim" CIRM-Funded Technology and CIRM-Funded Inventions. Patent applications often disclose a wide range of relevant developments in the field as background information, which means that a Grantee would have to find a way to flag and report completely unrelated patent applications to CIRM. It would be difficult enough to track patent applications that reference CIRM-funded *patented* inventions, especially for a large Grantee with multiple patent managers. But it would be impossible to track patent applications that reference unpatented inventions or CIRM-Funded Technology. And requiring third parties to report their own patent applications that "disclose" CIRM-Funded Inventions or CIRM-Funded Technology (and related funding) is inappropriate and completely unmanageable.

- We have some concerns with the new requirement to extend the reporting obligation to licensees and transferees. First, this added requirement seems redundant and unnecessary as the Grantee is already required to make such reports, whether it is the Grantee or another entity that is filing the patent application, executing the license, etc. Currently, it is up to the Grantee to determine how best to gather this information. In many cases, it is clear that the other party will not have the opportunity to patent or license any CIRM-Funded Inventions or CIRM-Funded Technology and the Grantee should be free to make that determination and act accordingly. In fact, such a reporting obligation could have negative consequences, as in the context of transferring a biological material to an academic researcher for use in their own NIH-funded research program. In that case, the recipient researcher will not be able to patent or license the CIRM-Funded Invention or CIRM-Funded Technology, as they are neither the creator nor the owner. But rather than encouraging the expeditious transfer of a material for research use, the CIRM regulations would actually slow the process by requiring a CIRM-funded Grantee to put a new and unusual provision in its MTA – counter to CIRM's own interests as expressed in 100604. We would ask that this new requirement be removed completely or replaced with a less prescriptive reminder that the Grantee continues to be responsible for these reports, even with respect to its licensees and transferees.

- It should be made clear that the revenue reporting requirement under (5) does not include sponsored research funding, particularly if the extension of the obligations of (1)-(6) to third parties is retained. For example, an academic researcher who receives some biological material (CIRM-Funded Technology) may use the results of his/her research to apply for NIH funding to pursue a line of inquiry further – and that future research might not even use the biological material. We would recommend that the parenthetic comment be modified to say: *"(whether from a License Agreement or otherwise, but not including non-profit research funding)"*.

- The fourth line of this provision mentions "Licensing Activities" which is not defined. Perhaps "License Agreements" was intended? Also, (iv) mentions a Collaborative Agreement, which is not defined. Presumably, this is an agreement entered into with a subawardee who contributed to the original research project. If so, the agreement would have ended when the project ended and continued reporting doesn't make sense.

100602(e): We note that the use of the vaguely defined term Collaborators in this section does not carry with it a context limiting the term to those who are collaborating within the scope of a CIRM-funded

project. To address this, we recommend that the Option B definition of Collaborator be used, modified as above. We also note that this provision now ends with an incomplete sentence.

100606(a): It may be entirely appropriate to require grantees to make reasonable efforts to develop and commercialize CIRM-Funded (patentable) Inventions. But, as discussed earlier in this letter, it is not appropriate to require similar efforts for CIRM-Funded Technology (data, research results, etc.), and would be a poor use of limited university resources. We would ask that "CIRM-Funded Technology or" be deleted. If that is unacceptable, we would ask that the requirement be limited to just those CIRM-Funded Technologies that lend themselves to commercialization - perhaps to *"CIRM-Funded Technologies with potentially useful application in the treatment and diagnosis of disease"*, or *"with potentially useful commercial application"*.

100606(b): This section requires that we attempt to negotiate non-exclusive licenses for development of CIRM-Funded Inventions or CIRM-Funded Technology that we elect not to develop or make them otherwise publicly available. As discussed elsewhere in this letter, the vast majority of CIRM-Funded Technology, the day-to-day research results, are not of broad interest, either scientifically or commercially. Even in the case of inventions, even if they are technically patentable, some have little or no scientific or commercial value. It would be fiscally irresponsible to invest in a patent application and spend the manpower resources necessary to attempt to license such inventions, and as discussed earlier, academic institutions simply do not license the broad range of what is included in CIRM-Funded Technology. But our only option here is to take steps to make these things publicly available. It simply does not make sense to expend effort pushing day-to-day research results into the public domain. We would ask that this be limited in some way. If the objective is to make sure other researchers (and maybe commercial entities?) have freedom to operate if we choose not to patent, then a better approach might be to require that, if Grantees choose not to develop or commercialize or license CIRM-funded research results, they must not assert any rights they may have in such research results against third parties (unless such action puts the Grantee at a competitive disadvantage with a competitor). Or if the objective is to make sure that commercially useful research results have a fighting chance, then perhaps the requirement can be limited to research results that are potentially commercially useful, though this would seem unnecessary as the march-in rights already address this concern. Or for maximum CIRM flexibility, without being overly burdensome for the Grantee, perhaps such action can be at CIRM's request.

100606(f): The general thrust of this "optional" subdivision is entirely consistent with the practice of the academic community. We would simply note that it is not actually necessary to reserve these rights in the context of a non-exclusive license.

100606(h): Many things that could constitute a material breach of a license agreement would not be relevant to CIRM, such as the use of the university's name or being late with a progress report, and many breaches are promptly cured. We think it is inappropriate, and would be distasteful to our licensees, to have to report *all* breaches to CIRM. We would recommend that this provision be limited to material breaches that are unresolved within a reasonable time of the Grantee giving notice of breach to its Exclusive Licensee, and/or those for which the Grantee is considering termination of the license.

100607(b), (e), (f) and (g): As was done in 100607(a), the obligations should apply only to the entity that is commercializing the Drug. We would suggest language parallel to that used in (a): *"...or an*

Exclusive Licensee that is commercializing a Drug..." In addition, in the first line of (f) and (g) we would suggest replacing "a Drug" with "the Drug".

100608(a): It is not clear what is intended by the addition of "results of CIRM-Funded Research." CIRM-Funded Inventions and CIRM-Funded Technology seem to cover the entire breadth of CIRM-Funded research results, so the additional phrase appears to be redundant. To avoid confusion, we would recommend that it be deleted. Also, in the second line "the Grantee" should probably be replaced with "it" – this is the structure used in (b) and seems to be what was intended.

100609: The "Grantee or Collaborator" structure here is a bit ambiguous. We recommend that the object of the sentence refer back to the subject, as in: *"at least one calendar day before **it** issues any press release..."*

100610(a), (b): As discussed at the very beginning of this letter, universities generally do NOT engage in exclusive licensing outside an intellectual property context, since the only way to provide exclusivity would be to withhold knowledge from everyone else, effectively establishing a trade secret. We simply cannot do this. Yet these provisions would allow CIRM to do just that with the results of our research -- to compel exclusive licensing of "unpatentable" Inventions and data, results, know-how, etc. (CIRM-Funded Technology). We acknowledge that the added sentence in (c) speaks to this, and at least establishes an intention. We are still uncomfortable with this decision being taken out of our hands and would greatly prefer that march-in be limited to arrangements regarding CIRM-Funded (patentable) Inventions.

100610(b): We greatly prefer Option B as it is more concise and more clear.

Again, we appreciate the opportunity to comment on the proposed intellectual property regulations. If you have any questions about any of our comments, please don't hesitate to contact us.

Sincerely,

William Tucker

William T. Tucker
Executive Director
Research Administration and
Technology Transfer

cc: Vice President Beckwith
Executive Director Auriti
Director Streitz