

## Appendix 4: Interview Protocols

---

### Interview Protocol: RESEARCHERS – PIONEERS

#### Nature of Tissue Engineering

We are first trying to establish the extent to which and in what ways is TE a unified, coherent field. Do the various sub-fields of TE (i.e. ??) share a single history or should we expect to see largely independent development histories of each of these sub-fields?

#### Historical Profile

We would like to understand what the definitions of TE in the mid-to-late 1980s reveal about the thinking and vision of the time. Could you tell us how researchers and funders at the time defined the bounds of TE?

When was the first time the term TE was used (that you know of)? Who was using it and to describe what research?

What were TE's precursor fields? I.e., what fields came together to make TE recognizable as a distinct field? When? Why did it happen then? What characteristics made it recognizable as a distinct field?

What were the key technical challenges in (what is now called) TE in the mid- to late-1980s (before the term TE was coined)? At the time, what was the relative importance of enabling technologies vs. applications? What was the relative weight of fundamental vs. applied research? How did these balances change over the years?

What were the key discoveries, inventions, insights, and technological breakthroughs that contributed to the field's emergence as a separate entity? Who/what were the people, institutes, and tools associated with these breakthroughs? What were the relationships between and among these entities?

#### International Influences

Who were the international players (people, places) in the late 1980s? How was the focus of research abroad different from research in the US? Are there some parts of the field that are further ahead internationally than others? How do US researchers leverage this?

Do US researchers collaborate often with international counterparts? What gaps does international research fill?

How is the funding or regulatory climate different in these countries?

What has been the impact of international efforts (Japan, Europe etc.) on the emergence and evolution of the field in general and on the work of the US researchers in particular?

#### Policy Lessons

What, if anything, do the emergence and evolution of TE tell us about how to recognize new fields worthy of promotion, and how to encourage their growth?

What were the earliest clues that pointed to the emergence of a concept for a new field?

Who recognized these clues? When, how, and why?

What steps were taken to "test" the concept? What were the results of the "tests", and what was done about it?

What vision(s) existed for the field at the beginning? What steps were taken to realize them? To what extent and in what ways can we say these steps were successful?

---

## **Interview Protocol: RESEARCHERS – NEW ENTRANTS**

### **Nature of Tissue Engineering**

We are first trying to establish the extent to which and in what ways is TE a unified, coherent field. Do the various sub-fields of TE (i.e. ??) share a single history or should we expect to see largely independent development histories of each of these sub-fields?

### **Historical Profile**

What were the key discoveries, inventions, insights, and technological breakthroughs that contributed to the field's emergence as a separate entity? Who/what were the people, institutes, and tools associated with these breakthroughs? What were the relationships between and among these entities?

### **Early Evolution (1990s)**

How has the field migrated and evolved since the late 1980s? How have research priorities changed? What are the technical challenges today?

How did creation of the formal field affect the development of research? Did it bring together, productively and to the advantage of the researchers, the various threads of research in different fields? Were there any advantages that came out of this "union?" How did the initial support shape the agenda of TE in the long run?

What mechanisms were used in the early 1990s to further progress (setting up Centers, set-aside funding mechanism, cross-agency task forces etc.)?

What is the status of the field today? Where are the major loci of research? What are the obstacles to progress today? How are they being addressed? Has there been any change in institutional or funding strategy? How about the involvement of the private sector?

Is research in any of the sub-fields further ahead than others? Why?

Given our goals for the project, who else would you recommend we speak with?

---

## **Interview Protocol: GOVERNMENT AGENCIES**

## **Role of Regulations**

What was the role of FDA (CDC depending on who we are talking to) in shaping the research agenda and progress (especially in more controversial areas like genetic manipulation, and use of stem cells)?

## **Institutional Effects**

(for NSF only) How did creating the intend to) resolve umbrella field TE (technical challenges in the field)?

What was the role of your agency in deliberately or serendipitously (through funding related or support of precursor fields such as enzyme engineering) creating the field?

Who was funding, what would today be considered TE research, in the 1970s and 80s? What was their focus (research, graduate education, clinical applications, networking etc.)? How did this support shape the agenda of TE and vice versa?

What was the difference in the strategies used by the different funding organizations? How did they support the field in different but perhaps similarly effective ways?

How did your organization mobilize the private sector (through SBIR or STTR grants or other programs like ATP)?

Who were the people (“the visionaries”) at NSF and elsewhere who recognized the need and value of creating the field? What did they have to do to get the field launched?

What was the role of the 1987 and 1988 NSF workshops and conferences? What other events or activities (funding students, establishing Centers, sponsoring meetings etc.) are relevant here? What was their direct/immediate impact? What is their long-term impact?

What has been the role and impact of the cross-agency task force MATES? Whose ideas was it? Did the task force really enable better coordination among federal agencies? How?

(for the head of PTEI, TES etc.) What other “institutional infrastructure” exists in TE? (E.g., professional societies, journals, regular meetings, formal consortia or other collaborative arrangements) What are the roles and relationships of these other entities?

## **International Influences**

Were the 1987 activities in some way motivated by the perception of losing the “US edge” in the field?

## **Policy Lessons**

What, if anything, do the emergence and evolution of TE tell us about how to recognize new fields worthy of promotion, and how to encourage their growth?

What were the earliest clues that pointed to the emergence of a concept for a new field?

Who recognized these clues? When, how, and why?

What steps were taken to "test" the concept? What were the results of the "tests", and what was done about it?

What vision(s) existed for the field at the beginning? What steps were taken to realize them? To what extent and in what ways can we say these steps were successful?

---

## **Interview Protocol: PRIVATE SECTOR**

### **Historical Profile**

What were the key technical challenges in (what is now called) TE in the mid- to late-1980s (before the term TE was coined)? At the time, what was the relative importance of enabling technologies vs. applications? What was the relative weight of fundamental vs. applied research? How did these balances change over the years?

What were the key discoveries, inventions, insights, and technological breakthroughs that contributed to the field's emergence as a separate entity? Who/what were the people, institutes, and tools associated with these breakthroughs? What were the relationships between and among these entities?

### **Role of the Private Sector and Clinical Applications**

What are some of the most important TE firms today? Which of these have been around since the 1980s? What are some of the most important TE products in the market? What are TE firms developing other than a TE product (software, testing methods, materials, etc.)

What was the role of the private sector and capital markets and your company in particular, in the emergence and early evolution of the field? In what ways did you contribute or change the nature or pace of research? Did you collaborate with any university-based or international researchers, or government agencies? For what purpose? How productive was this relationship?

Approx. what is the ratio of investments made in TE: private vs public funding? How has this ratio changed over the years?

What was the role of the clinical side? Did the urgency to develop clinical applications change the nature and direction of research or product development in industry?

### **Role of Regulations and the Government in General**

What was the role of regulatory bodies (FDA, CDC) in shaping the research agenda and progress (especially in more controversial areas like genetic manipulation, and use of stem cells)?

How did the government enhance or hinder the progress of TE in the marketplace?

How is the situation of the private sector in TE different in Europe, Japan and other countries?

What did the government do to support the private sector? What could it have done better?

### **Early Evolution (1990s)**

How has the field migrated and evolved since the late 1980s? How have research or product development priorities changed? What are the technical challenges today?

What is the status of the field today from the point of view of TE firms? Where are the major loci of research? What are the obstacles to progress today? How are they being addressed? Has there been any change in institutional or funding strategy?

(for PTEI or other industry consortia) What are the employment patterns in the field? In academia and industry? How have they changed since the early years of the field? What are they expected to be in the coming years?

### **Policy Lessons**

What, if anything, do the emergence and evolution of TE tell us about how to recognize new fields worthy of promotion, and how to encourage their growth?

What were the earliest clues that pointed to the emergence of a concept for a new field?

Who recognized these clues? When, how, and why?

What vision(s) existed for the field at the beginning? What steps were taken to realize them? To what extent and in what ways can we say these steps were successful?

---

## **Interview Protocol: OTHERS WHO HAVE WRITTEN ON THE FIELD**

### **Historical Profile**

We would like to understand what the definitions of TE in the mid-to-late 1980s reveal about the thinking and vision of the time. Could you tell us how researchers and funders at the time defined the bounds of TE?

When was the first time the term TE was used? Who was using it and to describe what research?

What were TE's precursor fields? I.e. what fields came together to make TE recognizable as a distinct field? When? Why did it happen then? What characteristics made it recognizable as a distinct field?

What were the key technical challenges in (what is now called) TE in the mid- to late-1980s (before the term TE was coined)? At the time, what was the relative importance of enabling technologies vs. applications? What was the relative weight of fundamental vs. applied research? How did these balances change over the years?

What were the key discoveries, inventions, insights, and technological breakthroughs that contributed to the field's emergence as a separate entity? Who/what were the people, institutes, and tools associated with these breakthroughs? What were the relationships between and among these entities?

### **Policy Lessons**

What, if anything, do the emergence and evolution of TE tell us about how to recognize new fields worthy of promotion, and how to encourage their growth?

What were the earliest clues that pointed to the emergence of a concept for a new field?

Who recognized these clues? When, how, and why? What vision(s) existed for the field at the beginning? What steps were taken to realize them? To what extent and in what ways can we say these steps were successful?