



**BEFORE THE US FOOD AND  
DRUG ADMINISTRATION**

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**ANTIBODY SYSTEMS, INC., §  
CITIZEN PETITION §**

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**AFFIDAVIT**

**STATE OF TEXAS §  
COUNTY OF TARRANT §**

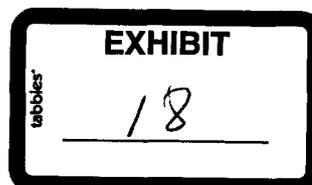
BEFORE ME, the undersigned Notary Public in and for Tarrant, County, Texas, on this day personally appeared Patricia H. Okimi, Ph.D, known to me, and having been duly sworn stated and deposed upon his oath the following:

1. My name is Patricia H. Okimi. I am resident of Tarrant, County, Texas. I hold the degree of Doctor of Philosophy and am on the faculty of the School of Nursing at the University of Texas at Arlington. I am over the age of 21 years, fully capable in law and fact to make this affidavit. Each of the statements made in this affidavit are based upon my personal knowledge unless otherwise stated.

2. In 199\_\_ the North Texas Institutional Review Board, (NTIRB) was formed under as I understand then existing regulations of the US Food and Drug Administration (FDA). The principal purpose of the NTIRB was to protect patients who might enroll in clinical trials for drug or device presented to the IRB for review and appropriate approval. The NTIRB ceased all operations and dissolved on or about \_\_\_\_\_, ~~1997~~ 2000

3. I became a full voting member of the NTIRB on or about September \_\_, 1991. The Chairman of the NTIRB was Dr. Neil Dishon, MD., head of student services at the University of Texas at Arlington.

4. To my knowledge, the NTIRB had 7 voting members and one alternate voting member. The public members were the Hon. Ambassador Robert Dean, Dr. Luther Felder, Pastor, and Lou Chapman of the newspaper, *Ft. Worth Star Telegram*. All were from the Arlington, Ft. Worth, Texas, area.



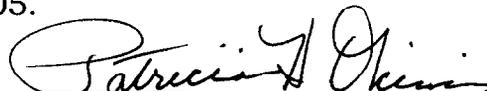
5. The NTIRB was to my personal knowledge at all times independent of Antibody Systems, Inc. Besides being a voting member I performed in an advisory capacity role. As member of NTIRB my duties were to review proposed protocols and consent forms, to suggest changes where appropriate, and to vote on each protocol presented to the NTIRB. During the term of the NTIRB I know we did operate as an IRB and at all times sought to comply with FDA law and regulation.

6. It is my understanding that Terry Fredeking, the President of Antibody Systems, Inc., of Hurst, Texas, received a warning letter from FDA for observations made into the operations of the NTIRB in April, 2003, and that he is in filing a Citizen's Petition in that regard. This affidavit is made in regard to that Citizen's Petition.

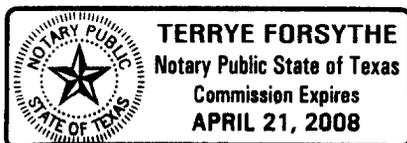
7. I was a voting member of the NTIRB during its entire existence and am personally familiar with the operations of the NTIRB. At no time during its existence did Antibody Systems, Inc. or Terry Fred eking, have any role, participation, or influence in the decisions or operations of the NTIRB. Antibody Systems, Inc., did submit proposed protocols as sponsor of products that required FDA approval, but it did not have any ownership interest in the NTIRB. Nor did Antibody Systems, or Mr. Fredeking participate in the management the NTIRB or in any vote.

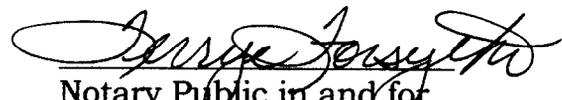
8. The NTIRB ceased operations and dissolved on or about 2000, ~~1999~~, because of reasons not related to Antibody Systems, Inc., or Mr. Fredeking.

Dated this 18<sup>th</sup> day of February, 2005.

  
Patricia H. Okimi, Ph. D

Subscribed and sworn to before me, on the 18<sup>th</sup> day of February,   , 2005, to certify which, witness my hand and official seal.



  
Notary Public in and for  
the State of Texas

My Commission Expires:

4/21/2008

TERRYE FORSYTHE  
Notary's Printed Name