

## **Condition of Participation Agreement for ANVIRZEL™ Treatment**

Salud Integral, S. A. de C. V. ("Salud Integral") is collecting ongoing clinical data for the use of the drug ANVIRZEL™, approved by the Health Secretary of Honduras, Sanitary Register Number M-07708. The clinical data collected is designed to gain additional information about the pharmacokinetics and pharmacodynamics of ANVIRZEL™, as well as to evaluate the effectiveness of ANVIRZEL™ in patients with particular diseases or conditions. The accuracy of the clinical data is dependent upon well-controlled and closely monitored conditions. Participation for treatment with ANVIRZEL™ is conditioned upon full compliance with the terms of this agreement. I understand that my failure to comply with the Condition of Participation could be detrimental to the assessment of the integrity and quality of the clinical data gained through my participation. I further understand that my participation in the clinical research with Salud Integral is subject to my compliance with the Condition of Participation and that any failure to comply may result in my rejection from any further participation in ANVIRZEL™ Therapy. Therefore, I agree to cooperate fully and comply with all of the Conditions of Participation set out herein below:

**A. Furnish Prior to Treatment – 1. Medical Records; 2. Patient Information; 3. Patient Consent Authorization; 4. Affirmation of Personal Use.**

**B. Acceptance Requirements for ANVIRZEL™ Treatment – 1. Provide continuing medical records and progress reports; 2. Purchase ANVIRZEL™ exclusively from Salud Integral to insure the consistency, integrity and quality of ANVIRZEL™ and the data produced thereby.**

**C. Acceptance By the Honduran Medical Review Board - I hereby understand that treatment is subject to acceptance by the Honduran Medical Review Board and agree to the terms of this Condition for Participation for ANVIRZEL™ Treatment.**

### **Acknowledgment for Use of Records**

I have voluntarily agreed and consented to be a participant ("Participant") in the continuing clinical research for the use of the drug ANVIRZEL™, approved by the Health Secretary of Honduras, Sanitary Register Number M-07708. I understand that as a result of my participation, my medical history, medical file and records as well as the data collected from my participation may be used for analysis and other research purposes for furthering the advancement of scientific knowledge for the use of ANVIRZEL™.

As a condition of participation in the clinical research of ANVIRZEL™, I (or my authorized representative) understand, acknowledge, and agree that information contained in my medical records including patient file, medical charts, x-rays, radiological studies, evaluations, history, notes, laboratory results, pictures, health-related records and documentation including any and all clinical information, statistics, data, analysis, or reports generated, compiled, produced, or developed from my participation in the research of ANVIRZEL™ ("Records") may be used by Salud Integral, SA de CV and its agents or affiliates ("Salud Integral") for purposes described herein.

These Records may be used for administering and conducting the continuing clinical research, analyzing and evaluating the research data and results, and publishing and/or presenting reports to individuals and other entities for the research, development, marketing, and distribution of ANVIRZEL™.

Salud Integral respects the need to protect the privacy of the research participants and will use its best efforts to maintain the security and confidentiality of all personal information found in or taken from the Records. Your personal information will not be used or disclosed for any purpose other than for the research and for the purposes stated above. Papers or any other works generated from the Records which describe the results of the research undertaken will be written and/or presented in such a way that no individuals can be directly identified, unless otherwise agreed.

### **Authorization for Release of Medical Records**

**TO: All Healthcare Providers**

**RE: Medical Records of:**

**RECIPIENT: Salud Integral**

I, or my authorized representative, authorize the release any medical information in my records including patient file, medical charts, x-rays, evaluations, notes, laboratory results and other tests results and documentation related to my care to the named recipient above for the purposes of medical evaluation and treatment. This consent to release information is good until the earlier of one year from the date written below or upon receipt of a written revocation of the authorization by me or my authorized representative. A facsimile or copy of this authorization shall be deemed the same as an original.

### **Consent to Assume Risks**

I am requesting permission for myself to receive ANVIRZEL™ therapy during the time period determined by my physician and in doing so I assume full responsibility for any and all risks of this action related to my current medical condition.

I have been informed by my physician as follows:

ANVIRZEL™ is a new drug approved for sale by the Secretary of Health of Honduras, C.A.

Because clinical data collection is ongoing:

The use of ANVIRZEL™ may be of unknown benefit; and

The use of ANVIRZEL™ may create unknown risks.

I understand that I am voluntarily requesting the use of ANVIRZEL™ and that my physician may not be knowledgeable of all the risks and hazards, if any, in the use of ANVIRZEL™. I acknowledge that there may be very little scientific information available about ANVIRZEL™.

I understand that there may be unanticipated side effects or symptoms as a result of using ANVIRZEL™, and that it is my responsibility to let the physician and other healthcare providers know if any unanticipated side effects or symptoms occur. If such side effects or symptoms occur, I understand that my physician may advise or direct the ANVIRZEL™ therapy be stopped.

I understand that no guarantee or assurance has been made to me as to the results that may be obtained from the use of ANVIRZEL™ or any side effects that may occur.

I hereby assume full responsibility for any or all risks of this action, and hereby release the following entities or individuals from any liability other than that stated herein and for any consequences that may result by my action in voluntarily consenting to the use and the receipt of ANVIRZEL™:

Phoenix Biotechnology, Inc., Addko, Inc., Drogueria Comercial Suprema, S. de R. L., Farmacia Salud Integral, S. de R.L., Salud Integral, S.A. de C. V., Drogueria Salud Integral, S. de R. L., Labortorios Y Distribuciones Francelia, S. de C. V. Corporacion, the referring physician, and investigating physician.

However, nothing in this consent shall be construed to waive or appear to waive any of my legal rights, to release or appear to release the physician, the sponsor, or its agents from liability for gross negligence.

With full knowledge that there are unknown benefits and unknown risks, I consent to the use of ANVIRZEL™ and assume full responsibility as a result of giving my consent.

**Signature of Patient or Authorized Representative below confirms Patients agreement to the terms of the Participation Agreement, Use of Medical Records, Release of Medical Records and Consent to Assume Risk.**

**Patient's Name:** \_\_\_\_\_

**Dated this:** \_\_\_\_\_ day of \_\_\_\_\_, 20 \_\_\_\_\_

\_\_\_\_\_  
**Signature of  
Patient or Patient's  
Authorized Representative**

\_\_\_\_\_  
**Witness**

*Please print, sign & date this form and then forward it via fax or email with your medical records.*