



Physician Instructions for Expanded Use Program aka Compassionate Use

Thank you for inquiring about an expanded use program otherwise known as compassionate use through AVM Biotechnology. We have put together some basic documents to help guide you and ensure compliance with the regulatory agencies. You are requesting to have access to an existing IND and our goal is to make this as easy and efficient as possible. Below we have outlined this process into 6 easy steps.

Prior to starting the process, please keep the following in mind:

As the requesting physician you are the sponsor and principal investigator of the expanded use and you must apply to the FDA for a single use Investigational New Drug number (IND)

- Your request must meet the following criteria to qualify as described in 21 CFR 56.102(d)
 - the patient is in a life-threatening condition that needs immediate treatment;
 - no generally acceptable alternative for treating the patient is available; and
 - because of the immediate need to use the device, there is no time to use existing procedures to get FDA approval for the use.
- If the above criteria is met, you can easily apply to AVM for access to our treatment by completing a **COMPASSIONATE USE APPLICATION**. And download the **Non-Disclosure and Confidentiality Agreement**. Print and sign these and either scan and email to: compassionateuse@avmbiotech.com or fax them back to AVM.

The rest of the application process is fairly simple and we are here to help facilitate this application. **It is split into the following steps.**

1 Contact the FDA for a single patient compassionate use Investigational New Drug (IND) number

AVM0703 is under the Division of Hematological Malignancies II (HMD2). Current officer for AVM0703 is Barbara Scepura, MS,, CRNP ph: **240-402-0004** and e-mail: ONCProjectFacilitate@fda.hhs.gov

The general phone number is ph: **301-796-7550** or fax: **301-796-9845**. Address: Food and Drug Administration, Center for Drug Evaluation and Research, Division of Hematologic Malignancies 2 (DHM2), 5901-B Ammendale Road Beltsville, MD 20705-1266. If for some reason, you can not get through, here is some general contact information for the FDA: **301-796-3400 or 855-543-3784**; fax: **301-431-6353**; or e-mail: druginfo@fda.hhs.gov. For questions about expanded access for emergency use for investigational biologics, contact CBER's Office of Communication, Outreach, and Development at phone: **240-402-7800 or 800-835-4709**; or e-mail: industry.biologics@fda.gov. For questions about non-emergency individual expanded access for biologics, contact CBER at: **240-402-8010 or 800-835-4709**.

2 Complete FDA form 3926

This will normally only take 45 minutes and we can help with any details. We have a few documents to help you understand the mechanism of action and rationale for treatment. The [Overview and Mechanism of Action](#) summary from our FDA applications can be found at the above link. You can also see a sample outline to the [Brief Clinical History](#) question. The [Single Patient Access Protocol](#) can be reviewed and downloaded. You should also submit just the first two pages of your CV with this form.

3 Obtain an Informed Consent from the patient or patient advocate

A generic form of an informed consent can be found at [INFORMED CONSENT TEMPLATE](#). You should also review the [exclusion and safety information](#) as well as [What Are The Risks?](#) This is to ensure that both you and your patient understand the risks and potential benefits. Keep a copy of the consent for the IRB submission.

4 Set up an Institutional Review Board meeting

You can request emergent use from the FDA by checking the box "Alternative IRB Review" on form 3926, however, you must still have an expedited review by the IRB chairperson as soon as possible. If you do not have access to an Institutional Review Board we can expedite your application through a third party IRB. Please note this on the application form. The emergency use provision is an exemption from prospective review and approval by the IRB. The exemption, which may not be used unless all of the conditions described in 21 CFR 56.102(d) exist, allows for one emergency use of a test article. These are typically situations in which the intent is not to conduct research but to act in the best interest of an individual patient. If you have a true emergency request, we can work with you to ensure your patient receives this treatment very quickly.

5 Request a Letter of Authorization (LOA) from AVM Biotechnology

We can normally send this within 24 hrs after receiving your IND number from the FDA. You will need to include this with your FDA 3926 form.

6 Set up a date and time for the treatment

Please allow up to 2 business days from the time of approved IND to the delivery of the drug to your institution or practice. We will provide you and/or your staff with a tracking number to ensure the drug is delivered prior to the scheduled treatment date. The date and place of the treatment as well as information on the key contact people involved in the treatment should be provided in the initial application.

If your hospital pharmacy requires a [PHARMACY MANUAL](#) we have included one through this link. In addition, we suggest you also complete the [PRODUCT PREPARATION FORM](#) to ensure quality control.

As a physician sponsor and investigator, you are required to report any adverse events to the FDA as well as AVM Biotechnology using standard acceptable forms of reporting as required by the FDA (Use FDA Form 3500A together with Form 1571). In addition, you are required to report the outcome of the treatment within 5 working days to your IRB as well as any adverse event you feel is due to the use of this treatment in an annual report.

We have found an excellent resource to help you and your colleagues navigate the compassionate use for your patients and their family members. Kids vs. Cancer publishes the [Compassionate Use Navigator](#) which is an excellent resource if you ever have questions.

Our goal is to help provide compassionate use of our product to your patient in the safest, most efficient manner and with the least amount of stress upon an already stressful situation. The cost of this medication will thus be provided free of charge for the patient you are sponsoring. We can also provide support to properly understand the dosing, potential side effects and the potential methods to prevent and or treat the side effects. If you have any questions or concerns about the treatment AVM Biotechnology has provided, please contact us anytime of the day or night. We are always available to answer any questions.