AALAS National Meeting 2023 – VA luncheon presentation

1200.07 VA Research with Animals: The New Directive and Its Companion Guide

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[1] VHA Handbook 1200.07 was released in 2011, scheduled for recertification 5 years later

Really not much changed from the version before it, VHA Handbook 1200.7, released in 2005

Work on real update to Handbook 1200.07 began in 2015

VHA Directive 1200.07 published 5/23/23 – complete revision

No fundamental changes, but lots of clarifications and simplifications, including

Harmonizing more with other existing requirements

Reducing the number of VA-specific requirements

Establishing as VA policy flexibilities that were introduced in response to COVID

Guidance for VHA Directive 1200.07 released 6/23/23

Focus today will be on how to use these two documents, so you will be able to find what you need

I‘m going to ZOOM through the slides, because the point is for you to get an impression of how the documents work, not to present specific details about the policy

If you have questions that we don’t address today, you can reach me at my VA email address (here) until November 30, when I will retire from VA

But the idea of this presentation is that you’ll be able to find the answers to a lot of your questions by using these two documents together.

As usual, these slides will be posted on the website for your reference later

[2] The new 1200.07 (the Directive) -- available on-line at www.research.va.gov

[3] Access Directive on-line

[4] The main change has to do with the new 1200.07 being a “Directive” instead of a “Handbook”

“Handbook” suggests a practical manual, to document policy but also put it into perspective

In contrast, a “Directive” is very focused, exclusively on

Explicit statements

Enforceable policy

Specific to VA research involving animals

∴ intentional emphasis on performance standards – getting hung up on wording of rules can be counterproductive

This means that we had to intentionally leave out of the Directive:

Requirements established somewhere else (AWR, PHS Policy, AAALAC Rules of Accreditation, other VA Directives) or their integration with requirements in 1200.07

Background/contextual information for interpreting requirements

Specific references to other documents (some mention of documents, not page and paragraph numbers)

Advice, recommendations, common effective approaches, guidance for implementation

I believe that all that is crucial to achieving the goals of the policy, so it all just got put into the separate companion guidance [5]

All the useful stuff is in the Guidance for 1200.07 -- How to understand and implement the requirements established by the Directive

Annotations and specific references – what do they say, and where do they say it?

Guidance for implementation

[Available online

Does not itself establish any enforceable requirements

How to find AR2023-002

[7] Look at the Directive and the Guidance together – note on the Contents pages:

Paragraph numbers and titles correspond exactly

Both are labeled in the header

Guidance has “GUIDANCE” watermark

Guidance is much longer

includes much more information than just the

explicit,

enforceable statements of policy

that are specific to VA research with animals

not intended for anyone to read straight through

think of this as a reference resource, like a dictionary,

where you just go to look things up

Paragraph 1 is “PURPOSE” [8]

Here is the text in the Directive – the purpose of the Directive

[9] Focus is on requirements and minimum standards

[10] the Guidance (also paragraph 1) – the purpose of the Guidance

Includes the purpose of the Directive and its focus on reqs. and minimum standards

Adds how the Guidance is intended to supplement the information in the Directive

[11] Look at Paragraph 2 “BACKGROUND”

Both the Directive and the Guidance address

Foundational principles

Federal regulatory and policy documents that VA policy requires compliance with

[12] But where the Directive provides

Simple statement of foundational principles

List of Federal regulatory and policy documents

The Guidance adds

Introductory information on how to use the Guidance

1. Expands the Foundation principles to provide specific information about

The Nuremberg Code – principle that research with human subjects is to be based on what has been learned from research with animals

The Declaration of Helskinki – foundation of current practices in research with human subjects

US Government Principles – for research with animals

1. Federal regulatory and policy documents – context and explanatory comments
2. (added, not in Directive) statement about interpretation of requirements being up to whoever imposes the requirements

[13] Paragraph 3 is DEFINITIONS, and illustrates a few more things

First, the Directive doesn’t contain any introduction, just goes right into a list of definitions

While the Guidance explains:

Definitions in the Directive are for the usages in the Directive

Where the Directive says to use someone else’s definition, the Guidance quotes what that someone else currently says

If a term is not defined, it is to be interpreted as in common usage

[14] If we look at some of the definitions, we can see how this works

The Directive gives a definition for “Affiliate”, and the Guidance has nothing to add

But the Guidance still shows the item for “Affliate”, and then indicates that there is “no additional guidance” – to keep the numbering in synch

For “Animal” the Directive says just “what they say”, so the Guidance

Fills in what they (PHS Policy and USDA AWR) currently say

Addresses what “related purposes” is understood to mean

Notes reference of AWR to dead animals (specific to licensing for dealers, exhibitors, operators of auction sales of animals) – N/A for research

[15] The definitions also provide an example of how the Guidance shows items that aren’t included in the Directive

Both have items q and r

[16] Guidance adds 3 items between q and r (that’s where they fit, alphabetically)

q+. Public Health Service (PHS) Assurance – not something defined by Directive 1200.07, but useful to know

q++. “PHS Policy” – “PHS Policy” vs “PHS policy” distinction as used in Directive 1200.07, but not definitions established by the Directive

q+++. VA Research – defined by 1200.01, not 1200.07, but useful to know

Next 6 paragraphs

4. POLICY – bottom line: VA requires programs to meet/exceed the accepted standards for care of animals in research

Directive – VA requirements to apply the standards more broadly

Guidance – provides more explanation

5. RESPONSIBILITIES -- This is where to look to figure out who is supposed to do what for the program

Directive – responsibilities that are assigned by the Directive

Guidance – relevant responsibilities regardless of who assigns them -- e.g. …

VHA Directive can’t assign responsibilities to the VA Secretary, so this is not included in the Directive

but the Guidance mentions compliance with legal requirements related to VA research with animals – which includes signing off, as required by current appropriations law, on any VA protocol with sensitive species, before the work can be done

(come back to paragraph 6 in a minute…)

7. VA ANIMAL RESEARCH PROGRAMS as a whole – addresses policies about the programs in general

Starting a program

Closing a program

Sharing oversight for Interinstitutional collaboration, and MOUs

Communication with the office of the CVMO – no local constraints allowed

8. THE VMU – policies about the facilities

Budget considerations

HVAC – overheat tests

Construction/renovation projects – review by CVMO

Security and access – including access to visitors

Emergency and disaster planning

9. GENERAL REQUIREMENTS for managing a program

Procurement of animals

Providing adequate veterinary care (written Program of Veterinary Care)

How IACUC oversight depends on the PHS Assurance

Need for USDA Registration

*Guidance adds info about methods of euthanasia and adherence to the AVMA Guidelines*

Go back to 6. TYPES OF IACUCS – defines three arrangements for IACUC oversight of VA programs, reflecting a refinement of the “internal” and “external” IACUCs we’ve had all along

[18] There’s a table in par 6 of the Guidance that summarizes in a table the options

Don’t go into the details now – just know to look here for …

The criteria for each type of IACUC

Where to find the details about how each one works

Paragraphs 10 and 11 are where we have all the details about IACUC function – what you are likely to refer to most often

[19] Paragraph 10 covers the “usual” IACUC (internal) – about ¾ of all VA programs

Paragraph 11 is about the external IACUCs (variations on internal IACUCs)

Last 6 paragraphs – pretty self-evident

[20] 12. ADOPTIONS

[20-1] 13. OCC HEALTH

[20-2] 14. CONFLICTS OF INTEREST – in conduct of IACUC business

[20-3] 15. TRAINING SPECIFIC TO VA RESEARCH WITH ANIMALS

[20-4] 16. (TRAINING) – ignore this

[20-5] 17. RECORDS MANAGEMENT – records retention

[20-6] 18. REFERENCES

[21] Done. Questions?