GW OHR Guidance:

Version Control for Study Documents

This guidance document will outline general best practices and strategies for maintaining accurate document versioning. This document should be used by investigators and research team members who would like more information about version control. For information about tracking versions in the iRIS system, please see the help document "Study Document Management Tips with iRIS" located in the iRIS help menu.

Why are version dates important?

Version control is a crucial part of effective document management. Maintaining accurate versions helps ensure the most up to date documents are used for study activities and updated during modifications. During an audit or quality check of a study, a version date will help create a document timeline and differentiate each change it has undergone.

Who is responsible for version control?

The primary investigator of the research study is responsible for version control but may delegate the responsibility to another study team member.

TIP: A good practice for principal investigators is implementation of a standard operating procedure (SOP) for research team members who author documents to update the version dates and numbers as they work.

What if a document has more than one version or date?

There are situations where a document may have multiple versions and dates from different organizations. For example, a sponsor may assign a version date to a template, the investigator may assign a version date, and the IRB stamp will include a date. In these instances, clear labeling of the dates can be helpful.

TIP: If you need a specific date listed in the IRB approval letter (often due to sponsor requirements) please include the version date in the file name of the document. This will help differentiate the version dates in the approval letter, as we cannot change the iRIS version dates.

EXAMPLE: A sponsor requires the consent form and protocol include the version 4.3 in the approval letter, but since this is the initial submission, the iRIS version dates are 1.0. The researcher saves the files in the following format "Consent Form Version 4.3" and "Protocol Version 4.3." When the approval letter automatically pulls the documents into the approval letter, the letter includes the following chart:

Submission Components Approved		
Document Type	Version	Date Approved
Consent Form Version 4.3	Version 1.0	10/25/2019
Protocol Version 4.3	Version 1.0	10/25/2019

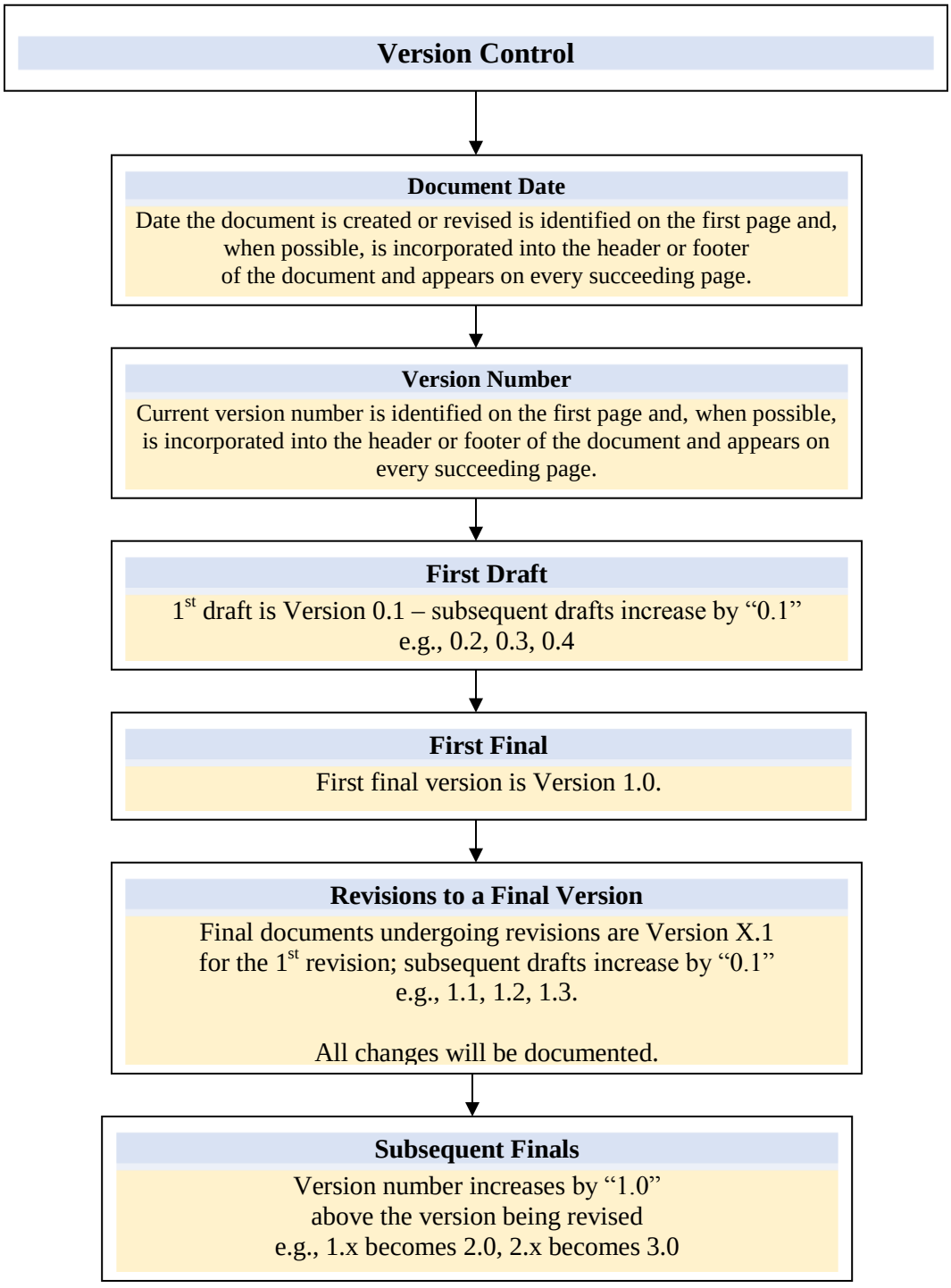
In the above example, the yellow highlighted boxes include the file names. Please include any document information you would like written in the approval letter in the file names of documents. The file names are auto populated in the iRIS approval letters.

Best practices for document dates and version numbers:

Document Dates	The author of the document will include the date the document is created or revised on the first page and into the header or footer of the document to appear on every succeeding page.
Version Numbers	The author of the document will include the new version number on the first page and into the header or footer of the document to appear on every succeeding page.

Recommended: Version Control Flowchart

Please note the versioning style below is not a requirement- it is to be used as a reference when versioning new documents. The chart can be found in the NIH Guidance Document: Version Control Guidelines linked on the last page of this document.



Questions?

George Washington University
Office of Human Research
(202) 994-2715
ohrirb@gwu.edu

References

NIH. (2013). Version Control Guidelines. Retrieved from: https://nccih.nih.gov/sites/nccam.nih.gov/files/CR-Toolbox/Version_Control_Guidelines_ver2_07-17-2015.pdf