

Certificates of Confidentiality by Funding Source – QUICK FACTS 2021

<u>NIH</u>	<ul style="list-style-type: none">✓ A CoC is included as a term and condition of award if funded by the NIH – no application required; CoC is only active for the term of the award✓ Non-funded researchers may apply to the NIH for a CoC if the research falls within the NIH CoC Policy and Mission. Researchers who apply for a CoC must first apply to the U-M HRPP.✓ Protections flow down to sub-awardees and sub-contractors. Primary awardees should inform sub-awardees/sub-contractors about CoC limitations and protections.✓ Allows for coverage of other unfunded collaborator/multi- site researchers with signed Assurances. However, U-M requires that unfunded collaborators/multi-site researchers obtain their own institutional CoC, if engaged.✓ Protections flow down when sharing identifiable datasets; researcher holding the CoC must inform recipient about the CoC limitations and protections
<u>CDC</u>	<ul style="list-style-type: none">✓ A CoC is included as a term and condition of award if funded by the NIH – no application required; CoC is only active for the term of the award✓ Non-Funded researchers may not apply to the CDC for a CoC – the CoC is only issued as part of a CDC award✓ Protections flow down to sub-awardees and sub-contractors. Primary awardees must inform sub-awardees/sub- contractors about CoC limitations and protections✓ Unfunded researchers must obtain their own CoC, if engaged (apply to NIH if research falls within the NIH CoC Policy and Mission)✓ Protections flow down when sharing identifiable datasets; researcher holding the CoC must inform recipient about the CoC limitations and protections
<u>FDA</u>	<ul style="list-style-type: none">✓ A CoC is a term and condition of award✓ CoCs are issued to FDA awardees (“mandatory” CoC) or upon application for non-federally funded researchers (“discretionary” CoC). Researchers who plan to apply for a discretionary CoC must first apply to the U-M HRPP.✓ For non-federally-funded research, the research must involve the use or study of a product subject to FDA’s jurisdiction and subject to FDA regulatory authority✓ Protections flow down when sharing identifiable datasets; researcher must inform recipient about CoC limitations and protections✓ Engaged unfunded collaborators/multi-site researchers must apply to NIH for a CoC.

<p><u>SAMHSA</u></p>	<ul style="list-style-type: none"> ✓ CoCs are for SAMHSA awardees only. However, the awardee <u>must apply</u> to SAMHSA to obtain documentation of the CoC. Researchers <u>must first apply to the U-M HRPP</u>. ✓ Collaborator/multi-site and sub-contractor researchers do not benefit from a SAMHSA CoC. Therefore, collaborator/multi-site and sub-contractor researchers should apply to NIH for a CoC, if engaged. ✓ Collaborator/multi-site and sub-contractor researchers do benefit from HRSA CoC with signed Assurances. However, U-M requires that unfunded collaborators/multi-sites obtain their own CoC, if engaged. ✓ Amendments/extensions apply ✓ Protections flow down when sharing identifiable datasets; researcher must inform recipient about the CoC limitations and protections
<p><u>HRSA</u></p>	<ul style="list-style-type: none"> ✓ CoCs are for HRSA awardees only. However, the awardee <u>must apply</u> to HRSA to obtain documentation of the CoC. Researchers <u>must first apply to the U-M HRPP</u>. ✓ Collaborator/multi-site and sub-contractor researchers do benefit from the HRSA CoC with signed Assurances. However, U-M requires that unfunded collaborators/multi-sites obtain their own CoC, if engaged. ✓ Amendments to the research that may affect the CoC must be submitted to the HRS; Extensions to renew the CoC must also be submitted. ✓ Protections flow down when sharing identifiable datasets; researcher must inform recipient about the CoC limitations and protections
<p>Other HHS Agency Funding</p>	<ul style="list-style-type: none"> ✓ Researchers may apply to the NIH for a CoC if the research falls within the NIH CoC <u>Policy</u> and <u>Mission</u>. Researchers who apply for a CoC <u>must first apply to the U-M HRPP</u>. ✓ Protections flow down to sub-awardees and sub-contractors. Primary awardees should inform sub-awardees/sub-contractors about CoC limitations and protections. ✓ Allows for coverage of other unfunded collaborator/multi- site researchers with signed Assurances. However, U-M requires that unfunded collaborators/multi-site researchers obtain their own institutional CoC, if engaged. ✓ Protections flow down when sharing identifiable datasets; researcher holding the CoC must inform recipient about the CoC limitations and protections
<p>Non-Federally Funded Research</p>	<ul style="list-style-type: none"> ✓ Researcher must apply directly to the NIH (or FDA if meet the specific requirements – see above) ✓ Protections flow down to sub-awardees and sub-contractors ✓ Allows for coverage of collaborator/multi- site researchers with signed Assurances. However, U-M requires that unfunded collaborators/multi-site researchers obtain their own CoC. ✓ Sharing identifiable datasets requires that researcher inform recipient about the CoC limitations and protections