### Certificates of Confidentiality by Funding Source – QUICK FACTS 2021

#### NIH
- 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.

#### CDC
- A CoC is included as a term and condition of award if funded by the CDC – no application required; CoC is only issued as part of a CDC 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.

#### FDA
- 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.
| **SAMHSA** | ✓ CoCs are for SAMHSA awardees only. However, the awardee must apply to SAMHSA to obtain documentation of the CoC. Researchers must first apply to the U-M HRPP.  
✓ 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 |
| **HRSA** | ✓ CoCs are for HRSA awardees only. However, the awardee must apply to HRSA to obtain documentation of the CoC. Researchers must first apply to the U-M HRPP.  
✓ 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 |
| **Other HHS Agency Funding** | ✓ 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 |
| **Non-Federally Funded Research** | ✓ 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 |