**SUBMISSION CHECKLIST**[ ]  Complete this form and upload it with your application materials in IRBNet.
Do not convert forms to .PDF format.

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| **INSTITUTIONAL REVIEW BOARD** |
| **IRB Application Form - Exempt Review** | [ ]  |
| **CITI Training Report (s)** Required of PI, Co-Inv., RAs and/or research advisor | **Human Research Course** | [ ]  |
| **Additional Course (only if required)** | [ ]  |
| **Informed Consent Form (or one for LAR)**Signature lines required, unless waived | [ ]  |
| **Recruitment or Data Access Permission Letter** Includes recruitment or data access at Marywood University | [ ]  |
| **Instruments**Provide reliability and validity evidence in application, if instruments are standardized. | **Survey/Questionnaire** | [ ]  |
| **Interview Questions** | [ ]  |
| **Demographic Questions** | [ ]  |
| **Data Collection Form** | [ ]  |
| **Professional Review of Instrument/Questions**Attach if you’ve created survey or questions or there’s no reliability/validity. Reviewer must be pro w/ Master’s degree or higher & not affiliated with study. | [ ]  |
| **Advertisements/Recruitment Materials**Email, Flyer, SONA Ad, Web or Social Media Post, phone script | [ ]  |

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| **EXEMPT REVIEW COMMITTEE** |
| **ERC Application Form - Exempt Review** | [ ]  |
| **CITI Training Report (s)** Required of PI, Co-Inv., RAs and/or research advisor | **Human Research Course** | [ ]  |
| **Additional Course (only if required)** | [ ]  |
| **Informed Consent Form (or one for LAR)**Signature lines not required | [ ]  |
| **Recruitment or Data Access Permission Letter** Includes recruitment or data access at Marywood University | [ ]  |
| **Instruments**Provide reliability and validity evidence in application, if instruments are standardized. | **Survey/Questionnaire** | [ ]  |
| **Interview Questions** | [ ]  |
| **Demographic Questions** | [ ]  |
| **Data Collection Form** | [ ]  |
| **Professional Review of Instrument/Questions**Attach if you’ve created survey or questions or there’s no reliability/validity. Reviewer must be pro w/ Master’s degree or higher & not affiliated with study. | [ ]  |
| **Advertisements/Recruitment Materials**Email, Flyer, SONA Ad, Web or Social Media Post, phone script | [ ]  |

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| **ADDITIONAL DOCUMENTS - DEPENDING ON POPULATION & ACTIVITIES**  |
| **Children (under age 18)** | [ ] [ ]  | Parental Permission Form (Consent)Child Assent Form or Script | **Non-English Speaking Participants** | [ ]  | Certification Form and Translated DocsTranslate **after** English version(s) finalized |
| **Receiving Protected Health Information from an area of MU that is a** [HIPAA Covered Entity](https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html) (MU clinic or behavioral/health-related service) | [ ]  | HIPAA Authorization Form |
| **Dietary Supplement** | [ ]  | [Dietary supplement](http://www.marywood.edu/irb/detail.html?id=269628&crumbTrail=Dietary%20Supplements&pageTitle=IRB:%20Dietary%20Supplements&title=Dietary%20Supplements) requirements addressed in application or as separate document. |
| [ ]  | Waiver of HIPAA Authorization for Research Form (only IRB or Privacy Board can waive) |
| **International Location for Recruitment or Activities** | [ ]  | [International Policy](http://www.marywood.edu/irb/detail.html?id=264311&crumbTrail=International%20Research&pageTitle=IRB:%20International%20Research&title=International%20Research) requirements addressed in application or as separate document. |
| **Waiver(s) of Informed Consent or Parental Permission** | [ ]  | Waiver of Documentation Form |
| [ ]  | Waiver or Alteration Form |

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| **CONTINUING REVIEW / ANNUAL RENEWALInstitutional Review Board** |
| Revisions to the Federal regulations concerning the protection of human subjects under 45 CFR 46 (The Common Rule) became fully effective on **January 21, 2019**. As a result, exempted and expedited studies approved on or after that date no longer require annual review (exception – if the IRB decides and documents why an expedited study requires annual review). However, **check-in report forms** are required annually if a study will continue beyond one year. Full studies require annual review, unless the IRB office determines that certain criteria which eliminate continuing review are met.Regardless of whether or not a study requires official annual renewal or just a check-in, the IRB and ERC maintain oversight throughout the entire life of a project.  |
| **IRB Continuing Review Application Form** | [ ]  |
| **Clean (Unstamped) Copies of Previously Approved Forms to Be Used in the Renewal Year*** Upon approval, the IRB will apply a stamp for the new approval period.
* These documents are not required if the only remaining activity is analysis of identifiable data (identifiable directly or indirectly via a code/key linking to identities).
 | **Informed Consent Form (or one for LAR)** | [ ]  |
| **Parental Permission Form** | [ ]  |
| **Child Assent Form or Script** | [ ]  |
| **Waiver of Documentation of Informed Consent/Parental Permission Form** | [ ]  |
| **Waiver or Alteration of Informed Consent/Parental Permission Form** | [ ]  |
| **Advertisements/Recruitment Materials** Email, Flyer, SONA Ad, Web or Social Media Post, phone script | [ ]  |
| **HIPAA Authorization or Waiver** | [ ]  |
| **Other:**       | [ ]  |
| **New or Updated Documents** Instruments, training report(s) for new investigators or study staff, advertisements, etc. | [ ]  |

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